

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.3	28.09.2024	9792591-00012	Date of first issue: 08.10.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier Trade name	: Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation
1.2 Relevant identified uses of t Use of the Sub-	he substance or mixture and uses advised against : Veterinary product
stance/Mixture	
Recommended restrictions on use	: Not applicable
1.3 Details of the supplier of the	e safety data sheet
Company	: MSD Kilsheelan Clonmel Tipperary, IE
Telephone	: 353-51-601000
E-mail address of person responsible for the SDS	: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2 Eye irritation, Category 2 Respiratory sensitisation, Category 1	H315: Causes skin irritation. H319: Causes serious eye irritation. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - single exposure, Category 3	H335: May cause respiratory irritation.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through pro- longed or repeated exposure.
Short-term (acute) aquatic hazard, Cate- gory 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Cat- egory 1	H410: Very toxic to aquatic life with long lasting effects.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

ersion .3	Revision Date: 28.09.2024		SDS Number: 0792591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021
.2 Label	elements			
Labe	lling (REGULATION	(EC)	No 1272/2008)	
Haza	rd pictograms	:		!
Signa	al word	:	Danger	• •
Haza	rd statements	:	H319 Causes H334 May cau difficulties if inha H335 May cau H361d Suspect H373 May cau repeated expose	ise respiratory irritation. ed of damaging the unborn child. ise damage to organs through prolonged or
Preca	autionary statements	:	Prevention:	
			P273 Avoid re	reathe dust. lease to the environment. otective gloves/ protective clothing/ eye protec- tion.
			Response:	
			CENTER/ docto	nfortable for breathing. Call a POISON r if you feel unwell. If experiencing respiratory symptoms: Call a ER/ doctor.
	rdous components wh	vich r		

Hazardous components which must be listed on the label: sulfadiazine Trimethoprim

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.3	28.09.2024	9792591-00012	Date of first issue: 08.10.2021

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
sulfadiazine	68-35-9 200-685-8	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Resp. Sens. 1; H334 STOT SE 3; H335 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 Acute toxicity esti- mate Acute oral toxicity: 1.500 mg/kg	41,67
Trimethoprim	738-70-5 212-006-2	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Bone marrow) Aquatic Chronic 2; H411	8,33

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.



Version 5.3	Revision Date: 28.09.2024	SDS Number: 9792591-000		
Prote	ction of first-aiders	and use th	esponders should pay attention to self-protection, ne recommended personal protective equipment potential for exposure exists (see section 8).	
If inhaled		If not brea If breathin	remove to fresh air. thing, give artificial respiration. g is difficult, give oxygen. cal attention.	
In case of skin contact		for at leas and shoes Get medic Wash clot	contact, immediately flush skin with plenty of water t 15 minutes while removing contaminated clothing s. cal attention. hing before reuse. ly clean shoes before reuse.	
In cas	se of eye contact	for at leas If easy to	contact, immediately flush eyes with plenty of wate t 15 minutes. do, remove contact lens, if worn. cal attention.	
If swallowed		Get medic	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.	
1.2 Most i	mportant symptoms	and effects, bot	h acute and delayed	
Risks		Causes se May cause ties if inha May cause Suspected	e respiratory irritation. d of damaging the unborn child. e damage to organs through prolonged or repeated	
		other resp	e exposure may aggravate preexisting asthma and iratory disorders (e.g. emphysema, bronchitis, reac ys dysfunction syndrome).	
4.3 Indica	tion of any immedia	te medical attent	ion and special treatment needed	
Treat	ment	: Treat sym	ptomatically and supportively.	

5.1 Extinguishing media						
Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2)				

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Versio 5.3	on	Revision Date: 28.09.2024		0S Number: 92591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021
				Dry chemical	
	Unsuita media	ble extinguishing	:	None known.	
5.2 S	pecial	hazards arising from	the	substance or mi	xture
Specific hazards during fire- fighting		:	concentrations, and potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. pustion products may be a hazard to health.	
Hazardous combustion prod- ucts		:	Carbon oxides		
5.3 A	dvice	for firefighters			
	Special protective equipment for firefighters		:		e, wear self-contained breathing apparatus. rective equipment.
	Specific ods	c extinguishing meth-	:	 Use extinguishing measures that are appropriate to loca cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe so. Evacuate area. 	

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).				
6.2 Environmental precautions				
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.		
6.3 Methods and material for co	ntain	ment and cleaning up		
Methods for cleaning up		Surround spill with absorbents and place a damp covering over the area to minimise entry of the material into the air. Add excess liquid to allow the material to enter into solution.		

with compressed air).

Soak up with inert absorbent material.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are re-

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
5.3		9792591-00012	Date of first issue: 08.10.2021
		Clean up remain bent. Local or nationa posal of this ma employed in the mine which regu Sections 13 and	atmosphere in sufficient concentration. ning materials from spill with suitable absor- al regulations may apply to releases and dis- terial, as well as those materials and items a cleanup of releases. You will need to deter- ulations are applicable. d 15 of this SDS provide information regarding national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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	 If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	 Do not get on skin or clothing. Do not breathe dust. 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.
	Already sensitised individuals, and those susceptible
	to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira- tory irritants or sensitisers.
	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. Do not eat, drink or smoke when using this product.
	Take care to prevent spills, waste and minimize release to the environment.
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



Version 5.3	Revision Date: 28.09.2024	SDS Number: 9792591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021	
		use of administ	rative controls.	
7.2 Condi	itions for safe storage,	including any inco	npatibilities	
Requirements for storage areas and containers		: Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.		
Advice on common storage		: Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases		
•	fic end use(s)			
Snec	ific use(s)	· No data available		

Specific use(s)

No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Dust

5 mg/m3 Value type (Form of exposure): TWA (respirable dust) Basis: FOR-2011-12-06-1358

10 mg/m3 Value type (Form of exposure): TWA (total dust) Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sulfadiazine	68-35-9	TWA	2 mg/m3 (OEB 1)	Internal
Trimethoprim	738-70-5	TWA	400 μg/m3 (OEB 2)	Internal

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
sulfadiazine	Water	0,01 mg/l
Trimethoprim	Water	0,9 mg/l

8.2 Exposure controls

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

Eye/face protection : Wear safety glasses with side shields or goggles.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version 5.3	Revision Date: 28.09.2024	SDS Number: 9792591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021	
Hand protection		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.		
Material		: Chemical-res	istant gloves	
Skin and body protection Respiratory protection		: If adequate lo sure assessn ommended g	or laboratory coat. ocal exhaust ventilation is not available or expo- nent demonstrates exposures outside the rec- uidelines, use respiratory protection. nould conform to NS EN 143	
Filter type		: Particulates t		

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling 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
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	6,5 - 8,5

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Ver 5.3	sion	Revision Date: 28.09.2024		92591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021
Viscosity Viscosity, kinematic Solubility(ies) Water solubility		:	Not applicable No data available	2	
		n coefficient: n-	:	Not applicable	-
	Vapour	pressure	:	Not applicable	
	Relative density		:	No data available	9
	Density		:	No data available	9
	Relativ	e vapour density	:	Not applicable	
		e characteristics ticle size	:	No data available	9
9.2		nformation			
	Explos	ves	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapor	ation rate	:	Not applicable	
	Molecu	ılar weight	:	No data available	9

SECTION 10: Stability and reactivity

Not classified as a reactivity hazard.

Stable under normal conditions.

10.3 Possibility of hazardous re	eactions
Hazardous reactions	 May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
10.4 Conditions to avoid	
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials

10.1 Reactivity

10.2 Chemical stability



Version 5.3	Revision Date: 28.09.2024		92591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021
Mate	rials to avoid	:	Oxidizing agents	
	ardous decomposition practication practication practication			
SECTION	N 11: Toxicological in	for	mation	
1.1 Infor	mation on hazard class	ses	as defined in Reg	ulation (EC) No 1272/2008
Inforr expo	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact	
	<mark>e toxicity</mark> lassified based on availa	hlo	information	
Prod		DIE	information.	
	e oral toxicity	:	Acute toxicity estine Method: Calculation	mate: > 2.000 mg/kg on method
<u>Com</u>	ponents:			
sulfa	diazine:			
Acute	e oral toxicity	:	LD50 (Mouse): 1.	500 mg/kg
Acute	e dermal toxicity	:	LD50 (Rat): > 5.00 Remarks: Based o	00 mg/kg on data from similar materials
	e toxicity (other routes of nistration)	:	LD50 (Rat): 880 n Application Route	
			LD50 (Mouse): 18 Application Route	
Trim	ethoprim:			
Acute	e oral toxicity	:	LD50 (Rat): 1.500) - 5.300 mg/kg
			LD50 (Mouse): 1.9	910 - 7.000 mg/kg
	e toxicity (other routes of nistration)	:	LD50 (Rat): 400 - Application Route	
			LD50 (Dog): 90 m Application Route	
			LD50 (Mouse): 13 Application Route	

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



rsion 3	Revision Date: 28.09.2024	SDS Numbe 9792591-00		
Skir	n corrosion/irritation			
Cau	ses skin irritation.			
<u>Con</u>	nponents:			
sulf	adiazine:			
Res Rem	ult narks	: Skin irrit : Based o	ation n data from similar materia	lls
	i ous eye damage/eye i ses serious eye irritatio			
<u>Con</u>	nponents:			
sulf	adiazine:			
Spe Res Rem			to eyes, reversing within 7 n data from similar materia	
Res	piratory or skin sensi	isation		
_	n sensitisation			
	classified based on ava	ilable information	n.	
	piratory sensitisation	a symptoms or	breathing difficulties if inha	aled
	nponents:			
	adiazine:			
Test	t Type	: Maximis	ation Test	
Spe		: Guinea		
Res	ult narks		n sensitizer. 1 data from similar materia	ls
Ren		. Dasca o		
Trin	nethoprim:			
	t Type		ation Test	
Expo Spe	osure routes	: Dermal	:~	
Res		: Guinea : Not a sk	n sensitizer.	
Gor	m cell mutagenicity			
	classified based on ava	ilable information	n.	
Con	nponents:			
sulf	adiazine:			
Gen	otoxicity in vitro	Result:	e: Bacterial reverse mutati egative :: Based on data from simi	• • •

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Version 5.3	Revision Date: 28.09.2024	SDS Number: 9792591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021			
		Test system: Result: negat	nromosomal aberration Chinese hamster ovary cells ive sed on data from similar materials			
Tri	methoprim:					
	enotoxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) ive			
		Test Type: C Result: negat	hromosomal aberration ive			
		Test Type: In Result: negat	vitro mammalian cell gene mutation test ive			
			NA damage and repair, unscheduled DNA syn- nmalian cells (in vitro) ive			
Ge	notoxicity in vivo	: Test Type: M	icronucleus test			
		Species: Rat	Species: Rat			
		Result: negat	IVe			
		Test Type: Cl Species: Hun Result: negat				
	rcinogenicity t classified based on availa	able information.				
Re	productive toxicity					
Su	spected of damaging the u	nborn child.				
<u>Co</u>	mponents:					
su	lfadiazine:					
Eff me	ects on foetal develop- ent	Result: Embr	ise			
Tri	methoprim:					
Eff	ects on fertility					

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



sion Revision Date 28.09.2024	e: SDS Number: 9792591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021
Effects on foetal deve ment	Species: Rat Application F Developmen Result: Effec	
	Result: Embi	
		t i
		nster
		obit
Reproductive toxicity sessment	- As- : Suspected o	f damaging the unborn child.
STOT - single expose May cause respiratory		
Components:		
sulfadiazine:		
Assessment	: May cause re	espiratory irritation.
STOT - repeated exp May cause damage to	o osure o organs through prolonge	ed or repeated exposure.
Components:		
Talas e (h. e a alas		
Trimethoprim:		

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.3	28.09.2024	9792591-00012	Date of first issue: 08.10.2021

Repeated dose toxicity

Components:

Trimethoprim:		
Species NOAEL LOAEL Application Route Exposure time Target Organs	: Rat : 100 mg/kg : 300 mg/kg : Oral : 6 Months : Bone marrow, Liver, Pituitary gland, Thyroid	
Species LOAEL Application Route Exposure time Target Organs	: Rat : 300 mg/kg : Oral : 3 Months : Bone marrow	
Species NOAEL LOAEL Application Route Exposure time Target Organs	 Dog 2,5 mg/kg 45 mg/kg Oral 3 Months Blood, Thyroid 	

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human	exposure
Components:	
sulfadiazine: General Information	: May cause eye, skin, and respiratory tract irritation.
Trimethoprim: Ingestion	: Target Organs: Bone marrow Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.3	28.09.2024	9792591-00012	Date of first issue: 08.10.2021

SECTION 12: Ecological information

12.1 Toxicity

Components:		
sulfadiazine:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Anabaena flos-aquae): 17 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Anabaena flos-aquae): 3,9 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 0,13 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		EC50 (Microcystis aeruginosa (blue-green algae)): 0,135 mg/l Exposure time: 7 Days Method: ISO 8692
M-Factor (Acute aquatic tox- icity)	:	1
Toxicity to microorganisms	:	EC50 : > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
		NOEC : 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to daphnia and other	:	NOEC: 6,2 mg/l

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Vers 5.3	sion	Revision Date: 28.09.2024		DS Number: 92591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021
	aquatic ic toxici	invertebrates (Chron- ty)		Exposure time: 2 [,] Species: Daphnia Method: OECD T	a magna (Water flea)
	M-Factor toxicity)	or (Chronic aquatic)	:	1	
	Trimet	hoprim:			
	Toxicity	to fish	:	LC50 (Pimephale Exposure time: 96	s promelas (fathead minnow)): 100 mg/l 6 h
		v to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48	nagna Straus): 92 mg/l 8 h
	Toxicity plants	v to algae/aquatic	:	EC50 (Pseudokiro mg/l Exposure time: 72	chneriella subcapitata (microalgae)): 80,3 2 h
				NOEC (Pseudoki mg/l Exposure time: 72	rchneriella subcapitata (green algae)): 16 2 h
				EC50 (Anabaena Exposure time: 72	flos-aquae): 253 mg/l 2 h
				EC10 (Anabaena Exposure time: 72	flos-aquae): 26 mg/l 2 h
	Toxicity	to microorganisms	:	EC10 : 16,7 mg/l Exposure time: 3 Test Type: Respin Method: OECD T	
				EC50 : > 1.000 m Exposure time: 3 Test Type: Respin Method: OECD T	hrs
	Toxicity icity)	v to fish (Chronic tox-	:	NOEC: 0,157 mg/ Exposure time: 2 ⁻ Species: Zebrafis	1 d
		v to daphnia and other invertebrates (Chron- ty)	:	NOEC: 6 mg/l Exposure time: 2 ⁻ Species: Daphnia	1 d a magna (Water flea)
12.2	12.2 Persistence and degradability		ity		
	Compo	onents:			
	sulfadi	azine:			
		radability	:	Result: Not readil	y biodegradable.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version 5.3	Revision Date: 28.09.2024		DS Number: '92591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021
			Biodegradation: Exposure time: 2 Method: OECD 1	
Trimethoprim: Biodegradability		:	Biodegradation: Exposure time: 2	
			Biodegradation: Exposure time: 2	
12.3 Bio	accumulative potential			
Con	nponents:			
Part	adiazine: ition coefficient: n- nol/water	:	log Pow: 0,12	
Part	nethoprim: ition coefficient: n- nol/water	:	: log Pow: 0,91	
	bility in soil data available			
12.5 Res	ults of PBT and vPvB a	isse	ssment	
	<u>duct:</u> essment	:	to be either persi	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 Enc	locrine disrupting prop	ertie	es	
	<u>duct:</u> essment	:	ered to have end REACH Article 5	nixture does not contain components consid- locrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.

12.7 Other adverse effects

No data available



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.3	28.09.2024	9792591-00012	Date of first issue: 08.10.2021

SECTION 13: Disposal considerations

13.1 Waste treatment methods	
Product	 Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	 Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

RID

14.1 UN number or ID number			
ADN	:	UN 3077	
ADR	:	UN 3077	
RID	:	UN 3077	
IMDG	:	UN 3077	
ΙΑΤΑ	:	UN 3077	
14.2 UN proper shipping name			
ADN	:	ENVIRONMENTALLY N.O.S. (sulfadiazine)	Y HAZARDOUS SUBSTANCE, SOLID,
ADR	:	ENVIRONMENTALLY N.O.S. (sulfadiazine)	Y HAZARDOUS SUBSTANCE, SOLID,
RID	:	ENVIRONMENTALLY N.O.S. (sulfadiazine)	Y HAZARDOUS SUBSTANCE, SOLID,
IMDG	:	ENVIRONMENTALLY N.O.S. (sulfadiazine)	Y HAZARDOUS SUBSTANCE, SOLID,
ΙΑΤΑ	:	Environmentally haza (sulfadiazine)	rdous substance, solid, n.o.s.
14.3 Transport hazard class(es)			
		Class	Subsidiary risks
ADN	:	9	
ADR	:	9	

: 9

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Ver 5.3	sion	Revision Date: 28.09.2024		OS Number: 92591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021
	IMDG		:	9	
	ΙΑΤΑ		:	9	
14.4	4 Packir	ng group			
	Classif	g group ication Code I Identification Number	:	III M7 90 9	
	Classif Hazaro Labels	g group ication Code I Identification Number restriction code	:	III M7 90 9 (-)	
	Classif	g group ication Code I Identification Number	:	III M7 90 9	
	IMDG Packin Labels EmS C	g group ode	:	III 9 F-A, S-F	
	aircraft Packin	g instruction (cargo	:	956 Y956 III Miscellaneous	
	Packin ger airc Packin	Passenger) g instruction (passen- craft) g instruction (LQ) g group	:	956 Y956 III Miscellaneous	
14.	5 Enviro	nmental hazards			
	ADN Enviror	nmentally hazardous	:	yes	
		nmentally hazardous	:	yes	
		nmentally hazardous	:	yes	
	IMDG Marine	pollutant	:	yes	



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.3	28.09.2024	9792591-00012	Date of first issue: 08.10.2021

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks

: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL	100 t	200 t
	HAZARDS		

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

AICS	:	not determined

DSL : not determined



Version 5.3	Revision Date: 28.09.2024		DS Number: 792591-00012	Date of last issue: 06.04.2024 Date of first issue: 08.10.2021
IECS	C	:	not determined	
	nical safety assessme al Safety Assessment h		ot been carried out	
SECTION	16: Other informat	ion		
Other	information	:		nges have been made to the previous version the body of this document by two vertical
Full te	ext of H-Statements			
H302			Harmful if swallow	ved.
H315		÷	Causes skin irrita	
H319		:	Causes serious e	
H334		:		y or asthma symptoms or breathing difficul-
H335			ties if inhaled. May cause respir	atony irritation
H3610	ł	÷		naging the unborn child.
H372	-	:		to organs through prolonged or repeated
H400		:	Very toxic to aqua	
H410		:	: Very toxic to aquatic life with long lasting effects.	
H411		:	Toxic to aquatic li	fe with long lasting effects.
	ext of other abbreviat	ions	5	
Acute		:	Acute toxicity	х <i>н</i> н
	ic Acute	:	Short-term (acute	
Eye Ir	ic Chronic rit	÷	Eye irritation	ic) aquatic hazard
Repr.		÷	Reproductive toxi	citv
	Sens.	:	Respiratory sensi	•
Skin I		:	Skin irritation	
STOT		:		gan toxicity - repeated exposure
STOT	SE 2011-12-06-1358	÷		gan toxicity - single exposure ional Exposure limits
	2011-12-06-1358 /	÷	Long term exposi	•
TWA				
Water Road; ing of tion (E of the Europ assoc cy Sc sociat borato	ways; ADR - Agreem AIIC - Australian Inver Materials; bw - Body w EC) No 1272/2008; CM German Institute for S ean Chemicals Agency iated with x% response hedule; ENCS - Existin ed with x% growth rat ory Practice; IARC - In	ent ntory veigl IR - Stand y; EC y; EL ig ar ie re terna	concerning the Int of Industrial Chem ht; CLP - Classifica Carcinogen, Mutag dardisation; DSL - C-Number - Europe x - Loading rate as hd New Chemical S sponse; GHS - Gl ational Agency for	tional Carriage of Dangerous Goods by Inland ernational Carriage of Dangerous Goods by nicals; ASTM - American Society for the Test- tion Labelling Packaging Regulation; Regula- gen or Reproductive Toxicant; DIN - Standard Domestic Substances List (Canada); ECHA - ean Community number; ECx - Concentration associated with x% response; EmS - Emergen- Substances (Japan); ErCx - Concentration as- obally Harmonized System; GLP - Good La- Research on Cancer; IATA - International Air the Construction and Equipment of Ships car-

SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Sulfadiazine (41%) / Trimethoprim (8%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.3	28.09.2024	9792591-00012	Date of first issue: 08.10.2021

rying 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

Aquatic Acute 1

Aquatic Chronic 1

Sources of key data used to compile the Safety Data Sheet	:	-	data from raw material SDSs, OECD sults and European Chemicals Agen- u/
Classification of the mixtur	e:		Classification procedure:
Skin Irrit. 2	H3 ⁻	15	Calculation method
Eye Irrit. 2	H3 ⁻	19	Calculation method
Resp. Sens. 1	H33	34	Calculation method
Repr. 2	H36	61d	Calculation method
STOT SE 3	H33	35	Calculation method
STOT RE 2	H37	73	Calculation method

H400 H410

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.

Calculation method

Calculation method



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
5.3	28.09.2024	9792591-00012	Date of first issue: 08.10.2021

NO / EN