

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier Trade name	:	Phthalylsulfathiazole / Sulfamerazine Formulation
1.2 Relevant identified uses of	the s	substance or mixture and uses advised against
Use of the Sub- stance/Mixture	:	Veterinary product
Recommended restrictions on use	:	Not applicable
1.3 Details of the supplier of th	e saf	ety 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)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 10 %



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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.

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Substances with a workplace exposure			
Phthalylsulfathiazole	85-73-4 201-627-4		>= 10 - < 20
Sulfamerazine	127-79-7 204-866-2		>= 1 - < 10

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 ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
Protection of first-aiders	:	No special precautions are necessary for first aid responders.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.



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In cas	e of skin contact	:	Wash with water Get medical atter	and soap. ntion if symptoms occur.
In cas	e of eye contact	:	If in eyes, rinse w Get medical atter	vell with water. ntion if irritation develops and persists.
lf swa	llowed	:	Get medical atter	NOT induce vomiting. ntion if symptoms occur. roughly with water.
4.2 Most important symptoms and effects, both acute and delayed				e and delayed
Risks		:	the skin.	t can cause mechanical irritation or drying of the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

— · · ·	
Treatment	

: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.

5.2 Special hazards arising from the substance or mixture

-			
	Specific hazards during fire- fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
	Hazardous combustion prod- ucts	:	Carbon oxides Nitrogen oxides (NOx) Sulphur oxides Metal oxides
5.3	Advice for firefighters		
	Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if nec- essary. Use personal protective equipment.

Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment.
		Use water spray to cool unopened containers.



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		SO.	nove undama cuate area.	ged containers from fire area if it is safe to do
SECTION	6: Accidental relea	se meas	sures	
6.1 Person	al precautions, prote	ctive equ	ipment and e	emergency procedures
Persor	nal precautions			ing advice (see section 7) and personal pro- t recommendations (see section 8).
6.2 Enviror	nmental precautions			
Enviro	nmental precautions	Pre Ret Loc	vent further le ain and dispos	he environment. akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages ned.
6.3 Method	Is and material for co	ntainme	nt and cleani	ng up
Method	ds for cleaning up	tain Avo with Dus es, leas Loc pos emp min Sec	er for disposa id dispersal of compressed at deposits sho as these may sed into the at al or national al of this mate oloyed in the o e which regula tions 13 and	f dust in the air (i.e., clearing dust surfaces

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	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe dust.
-		Handle in accordance with good industrial hygiene and safety
		practice, based on the results of the workplace exposure as-
		sessment
		Minimize dust generation and accumulation.

Commission Regulation (EU) 2020/878



PhthalyIsulfathiazole / Sulfamerazine Formulation

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Hygiene measures		:	 Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment. If exposure to chemical is likely during typical use, provide ey flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. 		
7.2 Condi	itions for safe storage,	inc	luding any incom	patibilities	
•	irements for storage s and containers	:	Keep in properly the particular nati	labelled containers. Store in accordance with ional regulations.	
Advid	ce on common storage	:	Do not store with Strong oxidizing a	the following product types: agents	
7.3 Speci	fic end use(s)				
-	ific use(s)	:	No data available	1	

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exp	osure 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 e Basis: FOR-2011-12-0	xposure): TWA (total dust) 06-1358		
Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
Phthalylsulfathia- zole	85-73-4	TWA	OEB 2 (>= 100 < 1000 μg/m3)	Internal	
Sulfamerazine	127-79-7	TWA	OEB 2 (>= 100 < 1000 µg/m3)	Internal	

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health ef-	Value
			fects	



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	Phthalylsulfathiazole	Workers	Inhalatior	h Long-term systemic effects	1,423 mg/m3
		Workers	Skin cont	act Long-term systemic effects	1,249 mg/kg bw/day
		Consumers	Inhalatior	h Long-term systemic effects	0,354 mg/m3
		Consumers	Skin cont	tact Long-term systemic effects	0,308 mg/kg bw/day
		Consumers	Ingestion	Long-term systemic effects	2,497 mg/kg bw/day
	Aluminum hydroxide	Workers	Inhalatior	h Long-term local ef- fects	10,76 mg/m3
		Workers	Inhalatior	h Long-term local ef- fects	10,76 mg/m3
		Consumers	Ingestion	Long-term systemic effects	4,74 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Phthalylsulfathiazole	Fresh water	0,191 mg/l
	Freshwater - intermittent	0,191 mg/l
	Marine water	0,019 mg/l
	Sewage treatment plant	2,51 mg/l
	Fresh water sediment	241,497 mg/kg
		dry weight (d.w.)
	Marine sediment	241,497 mg/kg
		dry weight (d.w.)
	Soil	111,906 mg/kg
		dry weight (d.w.)

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. 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.
Hand protection Material	:	Chemical-resistant gloves
Skin and body protection Respiratory protection	:	Work uniform or laboratory coat. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to NS EN 143



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	Filte	er type	:	Particulates type	(P)
SEC	CTION	9: Physical and che	mic	al properties	
9.1 I	I nforma Physica	ition on basic physica al state	ıl an :	d chemical prope fine powder	erties
	Colour		:	White to light yel	ow
	Odour		:	characteristic	
	Odour	Threshold	:	No data available)
	Melting	point/freezing point	:	No data available	9
	Initial b range	oiling point and boiling	:	No data available	
	Flamm	ability (solid, gas)	:	May form explosi dling or other me	ve dust-air mixture during processing, han- ans.
	Flamm	ability (liquids)	:	Not applicable	
		explosion limit / Upper bility limit	:	No data available	9
		explosion limit / Lower ability limit	:	No data available	
	Flash p	point	:	Not applicable	
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	рН		:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	Not applicable	
	Solubili Wat	ity(ies) er solubility	:	practically insolu	ble
	Partitio octanol	n coefficient: n- l/water	:	Not applicable	
	Vapour	pressure	:	Not applicable	



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	Relativ	ve density	:	No data availabl	e		
	Densit	у	:	No data availabl	e		
	Relativ	ve vapour density	:	Not applicable			
		e characteristics ticle size	:	No data availabl	e		
9.2	Other in	nformation					
	Explos	sives	:	Not explosive			
	Oxidizi	ing properties	:	The substance c	or mixture is not classified as oxidizing.		
	Evapo	ration rate	:	Not applicable			
	Molecu	ular weight	:	No data availabl	e		

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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				
Materials to avoid	Oxidizing agents			
10.6 Hazardous decomposition products				

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

In	formation on likely routes of	:	Inhalation
ex	posure		Skin contact
			Ingestion
			Eye contact



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Acute	e toxicity			
Not c	lassified based on ava	ailable	information.	
Com	oonents:			
Phtha	alylsulfathiazole:			
Acute	e oral toxicity	:	Method: OECD	ale): > 2.000 mg/kg Test Guideline 423 ne substance or mixture has no acute oral to
Acute	e dermal toxicity	:		.000 mg/kg Test Guideline 402 ne substance or mixture has no acute derma
Sulfa	merazine:			
Acute	oral toxicity	:	LD50 (Mouse):	25.000 mg/kg
Not c	corrosion/irritation lassified based on ava ponents:	ailable	information.	
Phtha	alylsulfathiazole:			
Speci	es	:	Rabbit	
Metho Resu		:	OECD Test Gu No skin irritation	
Resu	it.	•	NO SKITI ITILALIO	I
Serio	us eye damage/eye	irritati	on	
Not c	lassified based on ava	ailable	information.	
Com	oonents:			
Phtha	alylsulfathiazole:			
Speci		:	Rabbit	
Metho		:	OECD Test Gu	
Dear	4		No eye irritatior	l de la construcción de la const
Resu	lt		·	
	lt iratory or skin sensi	tisatio	on	

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.



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Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

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.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Phthalylsulfathiazole:

Ecotoxicology Assessment

Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded
Sulfamerazine: Toxicity to fish	:	LC50 (Morone saxatilis (striped bass)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 227 mg/l Exposure time: 48 h

12.2 Persistence and degradability

No data available



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12.3 Bioaccumulative potential

Components:

PhthalyIsulfathiazole:		
Partition coefficient: n- octanol/water	:	log Pow: -2
Sulfamerazine:		
Partition coefficient: n-	:	log Pow: 0,728

octanol/water

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment

: 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.

12.6 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.

12.7 Other adverse effects

No data available

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.



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SECTION 14: Transport information

14.1 UN number or ID number		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.3 Transport hazard class(es)		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.4 Packing group		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good
14.5 Environmental hazards		
Not regulated as a dangerous	aoa	nd

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.



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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 Parliam	nen	t and of the Council on the control of
major-accident hazards involving dangerous substances.		

Not applicable

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of other abbreviations

	Norway. Occupational Exposure limits Long term exposure limit
TWA	

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -



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European Chemicals Agency; EC-Number - European Community number; 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; 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; 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

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

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.

NO / EN