

Commission Regulation (EU) 2020/878

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.1	28.09.2024	5638035-00011	Date of first issue: 09.04.2020

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

1.1	Product identifier					
	Trade name	:	Sulfapyridine Formulation			
1.2	1.2 Relevant identified uses of the substance or mixture and uses advised against					
	Use of the Sub- stance/Mixture	:	Pharmaceutical			
	Recommended restrictions on use	:	Not applicable			
1.3	1.3 Details of the supplier of the 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)

Acute toxicity, Category 3 Skin sensitisation, Category 1 Reproductive toxicity, Category 1A Specific target organ toxicity - single exposure, Category 1 Long-term (chronic) aquatic hazard, Category 3 H301: Toxic if swallowed. H317: May cause an allergic skin reaction. H360F: May damage fertility. H370: Causes damage to organs.

H412: Harmful to aquatic life with long lasting effects.

### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) Hazard pictograms :



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



# Sulfapyridine Formulation

Version 4.1	Revision Date: 28.09.2024	SDS Num 5638035-		Date of last issue: 06.04.2024 Date of first issue: 09.04.2020
Signa	l word	: Dange	r	
Hazar	rd statements	: H301 H317 H360F H370 H412	May c May d Cause	if swallowed. ause an allergic skin reaction. amage fertility. es damage to organs. ful to aquatic life with long lasting effects.
Precautionary statements		: Prever		an acial instructions before use
		P201 P273 P280	Avoid Wear	n special instructions before use. release to the environment. protective gloves/ protective clothing/ eye tion/ face protection.
		Respo	nse:	
		P301 +		30 IF SWALLOWED: Immediately call a ON CENTER/ doctor. Rinse mouth.
		P308 +		exposed or concerned: Call a POISON ER/ doctor.
		P333 +		kin irritation or rash occurs: Get medical e/ attention.

## Hazardous components which must be listed on the label:

Sulfapyridine Benzyl cinnamate

### 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 combustible dust concentrations in air during processing, handling or other means.

## **SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

### Components

Index-No.	Chemical name		Classification	Concentration (% w/w)
-----------	---------------	--	----------------	--------------------------



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

# Sulfapyridine Formulation

ersion 1	Revision Date: 28.09.2024	SDS Number: 5638035-00011	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020	
Sulfa	pyridine	144-83-2 205-642-7	Acute Tox. 2; H300 Skin Sens. 1; H317 Repr. 1A; H360F STOT SE 1; H370 Aquatic Chronic 2; H411 Acute toxicity estimate Acute oral toxicity:	< 20
Benz	yl benzoate	120-51-4 204-402-9 607-085-00-9	15.8 mg/kg         Acute Tox. 4; H302         Aquatic Acute 1;         H400         Aquatic Chronic 2;         H411         M-Factor (Acute aquatic toxicity): 1         Acute toxicity estimate         Acute oral toxicity:         500 mg/kg	- < 1
	yl cinnamate	103-41-3 203-109-3	Skin Sens. 1B; H317 Aquatic Acute 1; H400 Aquatic Chronic 2; H411 M-Factor (Acute aquatic toxicity): 1	- < 1

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	:	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).
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.

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



# Sulfapyridine Formulation

Version 4.1	Revision Date: 28.09.2024	SDS Number: 5638035-0001	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020	
In cas	e of skin contact	of water. Remove co Get medica Wash cloth	contact, immediately flush skin with soap and plenty ntaminated clothing and shoes. I attention. ing before reuse. clean shoes before reuse.	
In cas	e of eye contact		nse well with water. I attention if irritation develops and persists.	
lf swal	lowed	Call a phys Rinse mout	d, DO NOT induce vomiting. ician or poison control centre immediately. h thoroughly with water. anything by mouth to an unconscious person.	
4.2 Most ir	nportant symptoms a	nd effects, both	acute and delayed	
Risks		May damag	an allergic skin reaction.	
		the skin.	h dust can cause mechanical irritation or drying of ct with the eyes can lead to mechanical irritation.	
4.3 Indicat	<b>4.3 Indication of any immediate medical attention and special treatment needed</b> Treatment : Treat symptomatically and supportively.			
riedu		. near symp	tomationly and supportivoly.	

## **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 t Specific hazards during fire- fighting		e substance or mixture Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides ucts

### 5.3 Advice for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.



Version 4.1	Revision Date: 28.09.2024	SDS Number: 5638035-00011	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020
for firefighters		Use personal pro	ptective equipment.
Specit ods	fic extinguishing meth-	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. aged containers from fire area if it is safe to do

## **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 pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions Environmental precautions		Avoid release to the environment.

nvironmental 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 containment and cleaning up

Methods for cleaning up	:	Sweep up or vacuum up spillage and collect in suitable con- tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or 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

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



# Sulfapyridine Formulation

Version 4.1	Revision Date: 28.09.2024	SDS Number: 5638035-00011	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020
Advice on safe handling Hygiene measures		Do not breat Do not swall Avoid contac Wash skin th Handle in ac practice, bas sessment Keep contain Keep contain Keep away f Take precau Do not eat, o Take care to environment : If exposure t flushing syst place. When work clothing Wash contar The effective engineering appropriate o industrial hys	et with eyes. horoughly after handling. cordance with good industrial hygiene and safety eed on the results of the workplace exposure as- ner tightly closed. st generation and accumulation. her closed when not in use. rom heat and sources of ignition. tionary measures against static discharges. Irink or smoke when using this product. prevent spills, waste and minimize release to the
7.2 Condi	tions for safe storage,	including any in	compatibilities
•	irements for storage and containers		perly labelled containers. Store locked up. Keep d. Store in accordance with the particular national
Advid	ce on common storage	Strong oxidiz	substances and mixtures
-	fic end use(s) ific use(s)	: No data avai	lable

## **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Petrolatum	8009-03-8	OELV - 8 hrs	5 mg/m3	IE OEL



Internal

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

# Sulfapyridine Formulation

Vers 4.1	ion Revision Da 28.09.2024			ate of last issue: 06.04.2024 ate of first issue: 09.04.2020	
			(TWA) (inhalable fraction)		
	Sulfapyridine	144-83-2	TWA	0.25 mg/m3 (OEB 2)	Internal

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

Wipe limit

Further information: DSEN

	. ,			
Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Benzyl benzoate	Workers	Inhalation	Long-term systemic effects	14.1 mg/m3
	Workers	Inhalation	Acute systemic ef- fects	70.5 mg/m3
	Workers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	2.48 mg/m3
	Consumers	Inhalation	Acute systemic ef- fects	12.4 mg/m3
	Consumers	Skin contact	Long-term systemic effects	1.42 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	1.42 mg/kg bw/day

0.1 mg/100 cm2

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

Substance name	Environmental Compartment	Value
Petrolatum	Oral (Secondary Poisoning)	9.33 mg/kg food
Benzyl benzoate	Fresh water	0.003 mg/l
	Marine water	0.322 µg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	2.043 mg/kg dry weight (d.w.)
	Marine sediment	0.204 mg/kg dry weight (d.w.)
	Soil	0.406 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

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

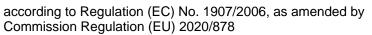
# Sulfapyridine Formulation

Version 4.1	Revision Date: 28.09.2024		Number: 035-00011	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020
Ma	aterial	: C	hemical-resista	nt gloves
Skin and body protection Respiratory protection		<ul> <li>Work uniform or laboratory coat.</li> <li>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387</li> </ul>		exhaust ventilation is not available or expo- demonstrates exposures outside the rec- lines, use respiratory protection.
Filter type				lates and organic vapour type (A-P)

## **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Physical state	:	solid
Colour	:	No data available
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 combustible dust concentrations in air during pro- cessing, handling or other means.
Flammability (liquids)	:	No data available
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	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Solubility(ies) Water solubility	:	No data available





# **Sulfapyridine Formulation**

Vers 4.1	sion	Revision Date: 28.09.2024		S Number: 38035-00011	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020
	Partitio octanol	n coefficient: n- /water	:	Not applicable	
	Vapour	pressure	:	Not applicable	
	Relative	e density	:	No data available	e
	Density	,	:	No data available	e
	Relative	e vapour density	:	Not applicable	
		characteristics icle size	:	No data available	e
9.2	Other in	formation			
	Explosi	ves	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	r mixture is not classified as oxidizing.
	Evapor	ation rate	:	Not applicable	
	Molecu	lar weight	:	No data availabl	e

## **SECTION 10: Stability and reactivity**

<b>10.1 Reactivity</b> Not classified as a reactivity haza	rd.			
10.2 Chemical stability				
Stable under normal conditions.				
10.3 Possibility of hazardous reaction	ons			
Hazardous reactions :	May form combustible dust concentrations in air during pro- cessing, handling 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.



Commission Regulation (EU) 2020/878

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.1	28.09.2024	5638035-00011	Date of first issue: 09.04.2020

## **SECTION 11: Toxicological information**

11.1	11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008					
li	nformation on likely routes of exposure		Inhalation Skin contact Ingestion Eye contact			
A	Acute toxicity					
Т	Foxic if swallowed.					
<u>F</u>	Product:					
Д	Acute oral toxicity	:	Acute toxicity estimate: 158 mg/kg Method: Calculation method			
<u>c</u>	Components:					
S	Sulfapyridine:					
A	Acute oral toxicity	:	LD50 (Rat): 15.8 mg/kg			
E	Benzyl benzoate:					
	Acute oral toxicity	:	Acute toxicity estimate: 500 mg/kg Method: Expert judgement Remarks: Based on national or regional regulation.			
A	Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg			
E	Benzyl cinnamate:					
	Acute oral toxicity	:	LD50 (Rat): 2,610 mg/kg Remarks: Based on data from similar materials			
A	Acute dermal toxicity	:	LD50 (Rabbit): > 5,000 mg/kg Remarks: Based on data from similar materials			
S	Skin corrosion/irritation					
Ν	Not classified based on availab	ole	information.			
<u>c</u>	Components:					
E	Benzyl benzoate:					
	Species	:	Rabbit			
	Method Result	:	OECD Test Guideline 404 No skin irritation			
E	Benzyl cinnamate:					
S	Species	:	Rabbit			
	Result	:	No skin irritation			
F	Remarks	:	Based on data from similar materials			

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



# **Sulfapyridine Formulation**

rsion	Revision Date: 28.09.2024	SDS Number: 5638035-00011	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020					
Serio	us eye damage/eye	irritation						
Not classified based on available information.								
<u>Com</u>	oonents:							
Benz	yl benzoate:							
Speci	es	: Rabbit						
Resu	lt	: No eye irritation						
Benz	yl cinnamate:							
Speci	-	: Rabbit						
Resu		: No eye irritation						
Rema	arks	: Based on data f	rom similar materials					
Respiratory or skin sensitisation								
Skin sensitisation								
May cause an allergic skin reaction. <b>Respiratory sensitisation</b> Not classified based on available information. <u>Components:</u>								
					Sulfa	pyridine:		
					Asses	ssment	: May cause sens	itisation by skin contact.
					Benz	yl benzoate:		
Test <sup>-</sup>	-	: Local lymph noc	le assay (LLNA)					
	sure routes	: Skin contact						
Speci		: Mouse						
Metho		: OECD Test Gui	deline 429					
Resu	It	: negative						
Benz	yl cinnamate:							
Test 7		: Maximisation Te	est					
	sure routes	: Skin contact						
Speci		: Guinea pig	deline 400					
Metho Rema		: OECD Test Guid	rom similar materials					
Reins	1172	. Daseu un udià li						
Asses	ssment	: Probability or ev rate in humans	idence of low to moderate skin sensitisat					
Germ	cell mutagenicity							
	lassified based on ava	ailable information.						
Com	oonents:							
<b>•</b> • • •								

## Sulfapyridine:

Genotoxicity in vitro

: Test Type: In vitro sister chromatid exchange assay in mam-

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



# Sulfapyridine Formulation

Version 4.1	Revision Date: 28.09.2024	SDS Number: 5638035-00011	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020
		malian cells Result: positiv	/e
			nromosome aberration test in vitro Chinese hamster cells ive
Genot	toxicity in vivo	: Test Type: Ma cytogenetic as Species: Mou Cell type: Bor Result: negati	se marrow
Germ sessn	cell mutagenicity- As- nent	: Weight of evic cell mutagen.	dence does not support classification as a germ
Benzy	yl benzoate:		
Genot	toxicity in vitro	: Test Type: Ba Result: negati	acterial reverse mutation assay (AMES) ive
		Test Type: In Result: negati	vitro mammalian cell gene mutation test ive
		Test Type: Ch Result: negati	nromosome aberration test in vitro ive
Genot	toxicity in vivo	mammalian liv Species: Rat Application Re Result: negati	nscheduled DNA synthesis (UDS) test with ver cells in vivo oute: Ingestion ive sed on data from similar materials
Benzy	yl cinnamate:		
-	toxicity in vitro	Method: OEC Result: negati	vitro mammalian cell gene mutation test D Test Guideline 476 ive sed on data from similar materials
		malian cells Result: negati	vitro sister chromatid exchange assay in mam- ive sed on data from similar materials
		Result: negati	acterial reverse mutation assay (AMES) ive sed on data from similar materials

## Carcinogenicity

Not classified based on available information.

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



# Sulfapyridine Formulation

ersion .1	Revision Date: 28.09.2024	SDS Number: 5638035-00011	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020
<u>Com</u>	ponents:		
Sulfa	pyridine:		
	nogenicity - Assess-	: No data avail	able
Benz	yl benzoate:		
Spec Appli Resu Rema	cation Route It	: Rat : Ingestion : negative : Based on dat	a from similar materials
Benz	yl cinnamate:		
	cation Route sure time It	: Rat : Ingestion : 105 weeks : negative : Based on dat	a from similar materials
	cation Route sure time It	: Mouse : Ingestion : 105 weeks : negative : Based on dat	a from similar materials
-	oductive toxicity damage fertility.		
<u>Com</u>	ponents:		
Sulfa	pyridine:		
Repro sessr	oductive toxicity - As- nent		ence of adverse effects on sexual function an numan epidemiological studies.
Benz	yl benzoate:		
	ts on fertility	Species: Rat Application R Result: negat	wo-generation reproduction toxicity study oute: Ingestion ive sed on data from similar materials
Effec ment	ts on foetal develop-	Species: Rat	mbryo-foetal development oute: Ingestion ive
Benz	yl cinnamate:		
	ts on fertility	reproduction/ Species: Rat	ombined repeated dose toxicity study with the developmental toxicity screening test oute: Ingestion
		Application R	

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



# Sulfapyridine Formulation

foetal develop- <b>ngle exposure</b> mage to organs. <u>nts:</u> line: routes	Result: negative Remarks: Base : Test Type: Emb Species: Rat Application Rou Result: negative	ed on data from similar materials pryo-foetal development ute: Ingestion
<b>ngle exposure</b> mage to organs. <u>nts:</u> line:	Species: Rat Application Rou Result: negative	ute: Ingestion e
mage to organs. nts: line:		
nts: line:		
line:		
outes		
nt		uce significant health effects in animals at cor 00 mg/kg bw or less.
beated exposure ed based on availal	ble information.	
dose toxicity		
nts:		
nzoate:		
	: Rat	
Route	: > 100 mg/kg : Ingestion	
ime	: 13 Weeks	
	: Based on data	from similar materials
	: Rat	
	: 781 mg/kg	
Davita	: 1,250 mg/kg	
i Route ime	: Skin contact : 4 Weeks	
inamate:		
	: Rat, male	
Route		
ime	: 90 Days	
-	: Based on data	from similar materials
1	Route	: Rat, male : 275 mg/kg Route : Ingestion ne : 90 Days : Based on data t

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



## Sulfapyridine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.1	28.09.2024	5638035-00011	Date of first issue: 09.04.2020

#### 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:**

#### Sulfapyridine:

Skin contact	:	Symptoms: Sensitisation
Ingestion	:	Symptoms: Gastrointestinal disturbance
		Symptoms: Sensitivity to light
		Symptoms: Headache
		Symptoms: hepatitis
		Symptoms: Stevens-Johnson syndrome

### **SECTION 12: Ecological information**

### 12.1 Toxicity

Components:

<u>components.</u>		
Sulfapyridine: Toxicity to algae/aquatic plants	:	EC10 (Raphidocelis subcapitata (freshwater green alga)): 1.0 mg/l End point: Growth rate Exposure time: 72 h
Benzyl benzoate:		
Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): 2.32 mg/l Exposure time: 96 h Method: Directive 67/548/EEC, Annex V, C.1.
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 3.09 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Raphidocelis subcapitata (freshwater green alga)): 0.475 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Raphidocelis subcapitata (freshwater green alga)): 0.247 mg/l Exposure time: 72 h

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



# Sulfapyridine Formulation

Versi 4.1	ion	Revision Date: 28.09.2024		OS Number: 38035-00011	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020
				Method: OECD T	est Guideline 201
	M-Fact icity)	or (Acute aquatic tox-	:	1	
	Toxicity	/ to microorganisms	:	EC50 (activated s Exposure time: 3 Method: ISO 819	
	Toxicity icity)	/ to fish (Chronic tox-	:	EC10: 0.032 mg/l Exposure time: 3 Species: Danio re Method: OECD T	5 d
i		/ to daphnia and other invertebrates (Chron- ity)	:		
	Benzyl	cinnamate:			
	-	/ to fish	:	LC50 (Danio rerio Exposure time: 90	o (zebra fish)): > 0.643 mg/l 6 h
		/ to daphnia and other invertebrates	:	Exposure time: 48 Test substance: \	agna (Water flea)): 2.8 mg/l 8 h Vater Accommodated Fraction est Guideline 202
	Toxicity plants	/ to algae/aquatic	:	ErC50 (Pseudoki mg/l Exposure time: 72 Method: OECD T	
				mg/l Exposure time: 72	chneriella subcapitata (green algae)): 0.122 2 h est Guideline 201
	M-Fact icity)	or (Acute aquatic tox-	:	1	
	Toxicity	/ to microorganisms	:	Exposure time: 3 Method: ISO 819	h
12.2	Persis	tence and degradabil	ity		
		onents:			
		benzoate:			

Biodegradability

: Result: Readily biodegradable.

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



# Sulfapyridine Formulation

Version 4.1	Revision Date: 28.09.2024	SDS Number: 5638035-00011	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020			
		Biodegradation Exposure tim Method: Direct				
Bon	zyl cinnamate:					
	egradability	Biodegradation Exposure tim				
12.3 Bioa	ccumulative potential					
Com	ponents:					
Benz	zyl benzoate:					
	tion coefficient: n- nol/water	: log Pow: 4 Method: OEC	D Test Guideline 117			
Parti	zyl cinnamate: tion coefficient: n- nol/water	: log Pow: 4.18 Method: OEC	3 D Test Guideline 117			
	<b>ility in soil</b> ata available					
	ults of PBT and vPvB a	issessment				
Prod	luct:					
	essment	to be either p	ce/mixture contains no components considered ersistent, bioaccumulative and toxic (PBT), or nt and very bioaccumulative (vPvB) at levels of er.			
12.6 End	ocrine disrupting prop	erties				
Prod	luct:					
	ssment	ered to have REACH Artic	e/mixture does not contain components consid- endocrine disrupting properties according to le 57(f) or Commission Delegated regulation 00 or Commission Regulation (EU) 2018/605 at 6 or higher.			
	er adverse effects ata available					
SECTIO	N 13: Disposal consi	derations				
13 1 Wae	13.1 Waste treatment methods					
Prod		: Dispose of in	accordance with local regulations.			

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



# Sulfapyridine Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Date of last issue: 06.04.2024
4.1		5638035-00011	Date of first issue: 09.04.2020
Conta	aminated packaging	are not produc Waste codes s discussion with Do not dispose : Empty containe dling site for re	te European Waste Catalogue, Waste Codes t specific, but application specific. hould be assigned by the user, preferably in the waste disposal authorities. of waste into sewer. ers should be taken to an approved waste han- cycling or disposal. e specified: Dispose of as unused product.

### **SECTION 14: Transport information**

### 14.1 UN number or ID number

UN 2811
UN 2811
UN 2811
UN 2811
UN 2811

ADN	: TOXIC SOLID, ORGANIC, N (Sulfapyridine)	.0.S.
ADR	: TOXIC SOLID, ORGANIC, N (Sulfapyridine)	.O.S.
RID	: TOXIC SOLID, ORGANIC, N (Sulfapyridine)	.0.S.
IMDG	: TOXIC SOLID, ORGANIC, N (Sulfapyridine)	.O.S.
ΙΑΤΑ	: Toxic solid, organic, n.o.s. (Sulfapyridine)	

## 14.3 Transport hazard class(es)

		Class	Subsidiary risks
ADN	:	6.1	
ADR	:	6.1	
RID	:	6.1	
IMDG	:	6.1	
ΙΑΤΑ	:	6.1	
14.4 Packing group			
<b>ADN</b> Packing group Classification Code Hazard Identification Number Labels		III T2 60 6.1	

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



## Sulfapyridine Formulation

Version 4.1	Revision Date: 28.09.2024	SDS Number: 5638035-00011	Date of last issue: 06.04.2024 Date of first issue: 09.04.2020
Classi Hazar Labels	ng group ification Code rd Identification Number s el restriction code	: III : T2 : 60 : 6.1 : (E)	
Classi	ng group ification Code d Identification Number s	: III : T2 : 60 : 6.1	
IMDG Packir Labels EmS (	ng group s	: III : 6.1 : F-A, S-A	
Packir aircrat Packir	ng instruction (LQ) ng group	: 677 : Y645 : III : Toxic	
Packir ger ai Packir	ng instruction (LQ) ng group	: 670 : Y645 : III : Toxic	
14.5 Envir	onmental hazards		
<b>ADN</b> Enviro	onmentally hazardous	: no	
<b>ADR</b> Enviro	onmentally hazardous	: no	
<b>RID</b> Enviro	onmentally hazardous	: no	
<b>IMDG</b> Marine	e pollutant	: no	

#### 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.



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.1	28.09.2024	5638035-00011	Date of first issue: 09.04.2020

### **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) : Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	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	
REACH - List of substances subject to authorisation (Annex XIV)	:	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
H2	ACUTE TOXIC	50 t	200 t

#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

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



## Sulfapyridine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.1	28.09.2024	5638035-00011	Date of first issue: 09.04.2020

#### 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 H-Statements

H300 :	Fatal if swallowed.
H302 :	Harmful if swallowed.
H317 :	May cause an allergic skin reaction.
H360F :	May damage fertility.
H370 :	Causes damage to organs if swallowed.
H400 :	Very toxic to aquatic life.
H411 :	Toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. Aquatic Acute Aquatic Chronic Repr. Skin Sens. STOT SE IE OEL		Acute toxicity Short-term (acute) aquatic hazard Long-term (chronic) aquatic hazard Reproductive toxicity Skin sensitisation Specific target organ toxicity - single exposure Ireland. List of Chemical Agents and Carcinogens with Occu- pational Exposure Limit Values - Code of Practice, Schedule 1
IE OEL / OELV - 8 hrs (TWA)	:	and 2 Occupational exposure limit value (8-hour reference period)

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 -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



Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.1	28.09.2024	5638035-00011	Date of first issue: 09.04.2020

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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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 Sheet		eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/

**Classification procedure:** 

#### Classification of the mixture:

		•
Acute Tox. 3	H301	Calculation method
Skin Sens. 1	H317	Calculation method
Repr. 1A	H360F	Calculation method
STOT SE 1	H370	Calculation method
Aquatic Chronic 3	H412	Calculation method

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.

IE / EN