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 28.09.2024 5638040-00011 Date of first issue: 09.04.2020 4.1

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

1.1 Product identifier

Trade name Sulfapyridine Formulation

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 Details of the supplier of the safety data sheet

**MSD** Company

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 H301: Toxic if swallowed.

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

Reproductive toxicity, Category 1A H360F: May damage fertility. Specific target organ toxicity - single ex-H370: Causes damage to organs.

posure, Category 1

Long-term (chronic) aquatic hazard, Cat-

egory 3

H412: Harmful to aquatic life with long lasting ef-

fects.

### 2.2 Label elements

### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal word Danger

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
 5638040-00011
 Date of first issue: 09.04.2020

Hazard statements : 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.

Precautionary statements : Prevention:

P201 Obtain special instructions before use. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P301 + P310 + P330 IF SWALLOWED: Immediately call a

POISON CENTER/ doctor. Rinse mouth.

P308 + P311 IF exposed or concerned: Call a POISON

CENTER/ doctor.

P333 + P313 If skin irritation or rash occurs: Get medical

advice/ 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

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		

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	5638040-00011	Date of first issue: 09.04.2020

Sulfapyridine	144-83-2	Acute Tox. 2; H300	>= 10 - < 20
Сапарупать	205-642-7	Skin Sens. 1; H317 Repr. 1A; H360F	7 10 120
		STOT SE 1; H370	
		Aquatic Chronic 2;	
		H411	
		Acute toxicity esti-	
		mate	
		Acute oral toxicity:	
		15,8 mg/kg	
Benzyl benzoate	120-51-4	Acute Tox. 4; H302	>= 0,25 - < 1
	204-402-9 607-085-00-9	Aquatic Acute 1; H400	
	007-005-00-9	Aquatic Chronic 2;	
		H411	
		M-Factor (Acute	
		aquatic toxicity): 1	
		Acute toxicity esti-	
		mate	
		Acute oral toxicity:	
		500 mg/kg	
Benzyl cinnamate	103-41-3 203-109-3	Skin Sens. 1B; H317	>= 0,25 - < 1
	203 103 3	Aquatic Acute 1;	
		H400	
		Aquatic Chronic 2;	
		H411	
		M-Factor (Acute	
		aquatic toxicity): 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.

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 28.09.2024 5638040-00011 Date of first issue: 09.04.2020 4.1

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Call a physician or poison control centre immediately.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks Toxic if swallowed.

May cause an allergic skin reaction.

May damage fertility. Causes damage to organs.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with 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

: Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides

ucts

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
 5638040-00011
 Date of first issue: 09.04.2020

#### 5.3 Advice for firefighters

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

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.

Remove undamaged containers from fire area if it is safe to do

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 pro-

tective 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 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 surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to 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

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
 5638040-00011
 Date of first issue: 09.04.2020

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, fume, gas, mist, vapours or spray.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

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. Contaminated work clothing should not be allowed out of the workplace.

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 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep in properly labelled containers. Store locked up. Keep tightly closed. 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

7.3 Specific end use(s)

Specific use(s) : No data available

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

## 8.1 Control parameters

### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form	Control parameters	Basis

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
 5638040-00011
 Date of first issue: 09.04.2020

		of exposure)		
Petrolatum	8009-03-8	TWA (Vapour)	50 mg/m3	FOR-2011-
		, , ,		12-06-1358
		TWA (Mist and	1 mg/m3	FOR-2011-
		particles)		12-06-1358
Sulfapyridine	144-83-2	TWA	0.25 mg/m3 (OEB 2)	Internal
	Further information: DSEN			
		Wipe limit	0.1 mg/100 cm2	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Benzyl benzoate	Workers	Inhalation	Long-term systemic effects	14,1 mg/m3
	Workers	Inhalation	Acute systemic effects	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 effects	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

# 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

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 28.09.2024 5638040-00011 Date of first issue: 09.04.2020 4.1

potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material Chemical-resistant gloves

Skin and body protection

Work uniform or laboratory coat.

Respiratory protection 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 14387

Filter type Combined particulates and organic vapour type (A-P)

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

9.1 Information on basic physical and chemical properties

solid Physical state

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

No data available Auto-ignition temperature

Decomposition temperature No data available

pΗ No data available

Viscosity

Viscosity, kinematic Not applicable

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
 5638040-00011
 Date of first issue: 09.04.2020

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : Not applicable

Molecular weight : No data available

## **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 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.

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
 5638040-00011
 Date of first issue: 09.04.2020

## **SECTION 11: Toxicological information**

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

Information on likely routes of : Inhalation exposure Skin contact

kposure Skin contact Ingestion

Eye contact

Acute toxicity

Toxic if swallowed.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: 158 mg/kg

Method: Calculation method

**Components:** 

Sulfapyridine:

Acute oral toxicity : LD50 (Rat): 15,8 mg/kg

Benzyl benzoate:

Acute oral toxicity : Acute toxicity estimate: 500 mg/kg

Method: Expert judgement

Remarks: Based on national or regional regulation.

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Benzyl cinnamate:

Acute oral toxicity : LD50 (Rat): 2.610 mg/kg

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Benzyl benzoate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Benzyl cinnamate:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

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
 5638040-00011
 Date of first issue: 09.04.2020

#### Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

Benzyl benzoate:

Species : Rabbit

Result : No eye irritation

Benzyl cinnamate:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

### Respiratory sensitisation

Not classified based on available information.

## **Components:**

Sulfapyridine:

Assessment : May cause sensitisation by skin contact.

Benzyl benzoate:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact

Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Benzyl cinnamate:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Remarks : Based on data from similar materials

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

#### Germ cell mutagenicity

Not classified based on available information.

# **Components:**

### 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
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.1
 28.09.2024
 5638040-00011
 Date of first issue: 09.04.2020

malian cells Result: positive

Test Type: Chromosome aberration test in vitro

Test system: Chinese hamster cells

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay)
Species: Mouse
Cell type: Bone marrow
Result: negative

Germ cell mutagenicity- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

Benzyl benzoate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Unscheduled DNA synthesis (UDS) test with

mammalian liver cells in vivo

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Benzyl cinnamate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

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

malian cells Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based 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**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.1
 28.09.2024
 5638040-00011
 Date of first issue: 09.04.2020

**Components:** 

Sulfapyridine:

Carcinogenicity - Assess-

ment

No data available

Benzyl benzoate:

Species : Rat
Application Route : Ingestion
Result : negative

Remarks : Based on data from similar materials

Benzyl cinnamate:

Species : Rat
Application Route : Ingestion
Exposure time : 105 weeks
Result : negative

Remarks : Based on data from similar materials

Species : Mouse
Application Route : Ingestion
Exposure time : 105 weeks
Result : negative

Remarks : Based on data from similar materials

Reproductive toxicity
May damage fertility.

Components:

Sulfapyridine:

Reproductive toxicity - As-

sessment

Positive evidence of adverse effects on sexual function and

fertility from human epidemiological studies.

Benzyl benzoate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Benzyl cinnamate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion

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
 5638040-00011
 Date of first issue: 09.04.2020

Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

## STOT - single exposure

Causes damage to organs.

#### **Components:**

#### Sulfapyridine:

Exposure routes : Oral

Assessment : Shown to produce significant health effects in animals at con-

centrations of 300 mg/kg bw or less.

### STOT - repeated exposure

Not classified based on available information.

## Repeated dose toxicity

### **Components:**

# Benzyl benzoate:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Remarks : Based on data from similar materials

Species : Rat
NOAEL : 781 mg/kg
LOAEL : 1.250 mg/kg
Application Route : Skin contact
Exposure time : 4 Weeks

#### Benzyl cinnamate:

Species : Rat, male
NOAEL : 275 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

## **Aspiration toxicity**

Not classified based on available information.

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 28.09.2024 5638040-00011 Date of first issue: 09.04.2020 4.1

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

**Product:** 

Assessment The substance/mixture does not contain components consid-

> ered 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:**

Sulfapyridine:

Toxicity to algae/aquatic

plants

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)):

EC10 (Raphidocelis subcapitata (freshwater green alga)): 1,0

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

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 5638040-00011 Date of first issue: 09.04.2020 4.1

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- : 1

icity)

Toxicity to microorganisms EC50 (activated sludge): > 10.000 mg/l

> Exposure time: 3 h Method: ISO 8192

Toxicity to fish (Chronic tox-

icity)

EC10: 0,032 mg/l Exposure time: 35 d

Species: Danio rerio (zebra fish) Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0,258 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Benzyl cinnamate:

LC50 (Danio rerio (zebra fish)): > 0,643 mg/l Toxicity to fish

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): 2,8 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): 0,386

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): 0,122

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

Toxicity to microorganisms EC50 : > 100 mg/l

Exposure time: 3 h Method: ISO 8192

Remarks: Based on data from similar materials

### 12.2 Persistence and degradability

## **Components:**

Benzyl benzoate:

Biodegradability Result: Readily biodegradable.

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
 5638040-00011
 Date of first issue: 09.04.2020

Biodegradation: 94 % Exposure time: 28 d

Method: Directive 67/548/EEC Annex V, C.4.D.

Benzyl cinnamate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 100 % Exposure time: 7 d

Remarks: Based on data from similar materials

### 12.3 Bioaccumulative potential

### **Components:**

Benzyl benzoate:

Partition coefficient: n- : log Pow: 4

octanol/water Method: OECD Test Guideline 117

Benzyl cinnamate:

Partition coefficient: n- : log Pow: 4,18

octanol/water Method: OECD Test Guideline 117

#### 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 consid-

ered 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

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
 5638040-00011
 Date of first issue: 09.04.2020

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**

#### 14.1 UN number or ID number

ADN : UN 2811
ADR : UN 2811
RID : UN 2811
IMDG : UN 2811
IATA : UN 2811

### 14.2 UN proper shipping name

**ADN** : TOXIC SOLID, ORGANIC, N.O.S.

(Sulfapyridine)

ADR : TOXIC SOLID, ORGANIC, N.O.S.

(Sulfapyridine)

RID : TOXIC SOLID, ORGANIC, N.O.S.

(Sulfapyridine)

IMDG : TOXIC SOLID, ORGANIC, N.O.S.

(Sulfapyridine)

IATA : 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
IATA : 6.1

### 14.4 Packing group

**ADN** 

Packing group : III
Classification Code : T2
Hazard Identification Number : 60

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
 5638040-00011
 Date of first issue: 09.04.2020

Labels : 6.1

**ADR** 

Packing group : III
Classification Code : T2
Hazard Identification Number : 60
Labels : 6.1
Tunnel restriction code : (E)

RID

Packing group : III
Classification Code : T2
Hazard Identification Number : 60
Labels : 6.1

**IMDG** 

Packing group : III
Labels : 6.1
EmS Code : F-A, S-A

IATA (Cargo)

Packing instruction (cargo : 677

aircraft)

Packing instruction (LQ) : Y645
Packing group : III
Labels : Toxic

IATA (Passenger)

Packing instruction (passen: 670

ger aircraft)

Packing instruction (LQ) : Y645
Packing group : III
Labels : Toxic

14.5 Environmental hazards

**ADN** 

Environmentally hazardous : no

ADR

Environmentally hazardous : no

RID

Environmentally hazardous : no

**IMDG** 

Marine 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.

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 28.09.2024 5638040-00011 Date of first issue: 09.04.2020 4.1

## **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 applicable

Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

(Annex XIV)

Regulation (EC) on substances that deplete the ozone

layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament 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

H2 200 t **ACUTE TOXIC** 50 t

#### 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

**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
 5638040-00011
 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. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Repr. : Reproductive toxicity Skin Sens. : Skin sensitisation

STOT SE : Specific target organ toxicity - single exposure

FOR-2011-12-06-1358 : Norway. Occupational Exposure limits

FOR-2011-12-06-1358 / : 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 -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

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
 5638040-00011
 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; 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 compile the Safety Data

Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

### Classification of the mixture: Classification procedure:

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.

NO / EN