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



Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin Formulation

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

1.1 Product identifier

Trade name : Benzylpenicillin / Dihydrostreptomycin Sulphate / Nafcillin

Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

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)

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or

breathing difficulties if inhaled.

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

Specific target organ toxicity - repeated H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Aspiration hazard, Category 1 H304: May be fatal if swallowed and enters air-

ways.

Long-term (chronic) aquatic hazard, Cat-

egory 4

H413: May cause long lasting harmful effects to

aquatic life.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms

Signal word : Danger

Hazard statements : H304 May be fatal if swallowed and enters airways.

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breath-

ing difficulties if inhaled.

H373 May cause damage to organs through prolonged

or repeated exposure.

H413 May cause long lasting harmful effects to aquatic

life.

Precautionary statements : Prevention:

P273 Avoid release to the environment.

P280 Wear protective gloves.

Response:

P301 + P310 IF SWALLOWED: Immediately call a POISON

CENTER/ doctor.

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P331 Do NOT induce vomiting.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

Hazardous components which must be listed on the label:

Paraffin oil

Benzylpenicillin

Dihydrostreptomycin sulphate

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.

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



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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Paraffin oil	8012-95-1 232-384-2	Asp. Tox. 1; H304 Aquatic Chronic 4; H413	>= 70 - < 90
Benzylpenicillin	61-33-6 200-506-3	Resp. Sens. 1A; H334 Skin Sens. 1B; H317 Aquatic Acute 1; H400 Aquatic Chronic 3; H412 M-Factor (Acute aquatic toxicity): 1	>= 10 - < 20
Sodium [2S-(2α,5α,6β)]-6-[[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate	985-16-0 213-574-4		>= 1 - < 10
Dihydrostreptomycin sulphate	5490-27-7 226-823-7	STOT RE 1; H372 (ear, Kidney, inner ear)	>= 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 : 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.

If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

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



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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 : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

If vomiting occurs have person lean forward.

Call a physician or poison control centre immediately. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May be fatal if swallowed and enters airways.

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

May cause damage to organs through prolonged or repeated

exposure.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

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- :

ucts

Carbon oxides Metal oxides

4/21

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



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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.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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.

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



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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.

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.

Already sensitised individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira-

tory irritants or sensitisers.

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

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



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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Paraffin oil	8012-95-1	OELV - 8 hrs (TWA) (inhalable fraction)	5 mg/m3	IE OEL
Benzylpenicillin	61-33-6	TWA	600 μg/m3 (OEB 2)	Internal
	Further information: RSEN, DSEN			
		Wipe limit	100 μg/100 cm2	Internal
Sodium [2S- (2α,5α,6β)]-6-[[(2- ethoxy-1- naph- thyl)carbonyl]amin o]-3,3-dimethyl-7- oxo-4-thia-1- azabicy- clo[3.2.0]heptane- 2-carboxylate	985-16-0	TWA	0.7 mg/m3 (OEB 2)	Internal
	Further information: RSEN			
Dihydrostreptomy- cin sulphate	5490-27-7	TWA	0.4 mg/m3 (OEB 2)	
	Further information: OTO			
		Wipe limit	Not required	

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Paraffin oil	Workers	Inhalation	Long-term systemic effects	5 mg/m3
	Workers	Inhalation	Short-term exposure	5 mg/m3
	Workers	Inhalation	Long-term local ef- fects	5 mg/m3
	Workers	Inhalation	Acute local effects	5 mg/m3

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

Substance name	Environmental Compartment	Value
Benzylpenicillin	Water	0.014 ma/l

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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



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All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

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 : 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 I.S. 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

Physical state : suspension

Colour : white to off-white

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling :

range

No data available

Flammability (solid, gas) : Not applicable

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 : No data available

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Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, dynamic : 300 - 16,000 mPa.s

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

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 : Can react with strong oxidizing agents.

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10.4 Conditions to avoid

Conditions to avoid : None known.

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

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Paraffin oil:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

Benzylpenicillin:

Acute oral toxicity : LD50 (Rat): 8,000 mg/kg

LD50 (Mouse): > 5,000 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Mouse): 3,500 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): 329 mg/kg Application Route: Intravenous

Sodium [2S- $(2\alpha,5\alpha,6\beta)$]-6-[[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Acute oral toxicity : LDLo (Rat): > 5,000 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Dog): 633 mg/kg

Application Route: Intravenous

LD50 (Mouse): 1,000 mg/kg

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Application Route: Intravenous

LD50 (Rat): 1,100 mg/kg Application Route: Intravenous

LD50 (Rat): 2,800 mg/kg

Application Route: Intramuscular

LD50 (Rat): 1,200 mg/kg

Application Route: Intraperitoneal

Dihydrostreptomycin sulphate:

Acute oral toxicity : LD50 (Rat): 9,000 - 25,000 mg/kg

LD50 Oral (Mouse): 30,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Paraffin oil:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Paraffin oil:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

Benzylpenicillin:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Dermal Species : Mouse

Result : Weak sensitizer

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Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig Result : positive

Remarks : Based on data from similar materials

Result : Strong sensitizer

Remarks : Based on human experience.

Germ cell mutagenicity

Not classified based on available information.

Components:

Benzylpenicillin:

Germ cell mutagenicity- As-

Weight of evidence does not support classification as a germ

sessment

cell mutagen.

Sodium [2S- $(2\alpha,5\alpha,6\beta)$]-6-[[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Germ cell mutagenicity- As-

Weight of evidence does not support classification as a germ

sessment

cell mutagen.

Dihydrostreptomycin sulphate:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Test system: Human lymphocytes

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Sodium [2S- $(2\alpha,5\alpha,6\beta)$]-6-[[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Carcinogenicity - Assess- : Weight of evidence does not support classification as a car-

ment cinogen

Dihydrostreptomycin sulphate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years

NOAEL : 5 mg/kg body weight

Result : negative

Reproductive toxicity

Not classified based on available information.

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Components:

Benzylpenicillin:

Effects on fertility : Test Type: Fertility

Species: Mouse

Result: No effects on fertility

Test Type: Fertility Species: Rat

Result: No effects on fertility

Test Type: Fertility Species: Rabbit

Result: No effects on fertility

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse

Result: No effects on foetal development

Test Type: Development

Species: Rat

Result: No effects on foetal development

Test Type: Development

Species: Rabbit

Result: No effects on foetal development

Sodium [2S- $(2\alpha,5\alpha,6\beta)$]-6-[[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

General Toxicity Maternal: NOAEL: 4,000 mg/kg body weight Developmental Toxicity: NOAEL: 4,000 mg/kg body weight Symptoms: No foetal abnormalities, No maternal effects

Dihydrostreptomycin sulphate:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Oral

Developmental Toxicity: NOAEL: 5 mg/kg body weight

Test Type: Embryo-foetal development

Species: Guinea pig

Application Route: Intramuscular

General Toxicity Maternal: LOAEL: 100 - 200 mg/kg body

weiaht

Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: Maternal toxicity observed., Embryotoxic effects and

adverse effects on the offspring were detected.

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



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STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Dihydrostreptomycin sulphate:

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Paraffin oil:

Species : Rat, female LOAEL : 161 mg/kg Application Route : Ingestion Exposure time : 90 Days

Dihydrostreptomycin sulphate:

Species : Guinea pig
LOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 90 d
Target Organs : ear

Symptoms : hearing loss

Species : Cat
LOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 60 d
Target Organs : ear

Symptoms : ataxia, hearing loss, Reduced body weight

Species : Cat
LOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 21 d
Target Organs : ear

Symptoms : ataxia, hearing loss, Reduced body weight

Aspiration toxicity

May be fatal if swallowed and enters airways.

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Components:

Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

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:

Benzylpenicillin:

Inhalation : Symptoms: Allergic reactions, Abdominal pain, bron-

chospasm, skin rash

Sodium [2S- $(2\alpha,5\alpha,6\beta)$]-6-[[(2-ethoxy-1-naphthyl)carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate:

Skin contact : Target Organs: Skin

Symptoms: Dermatitis

Target Organs: Respiratory system

Symptoms: Sensitisation

Ingestion : Target Organs: Gastrointestinal tract

Symptoms: Diarrhoea

Target Organs: Respiratory system

Symptoms: anaphylaxis Target Organs: Kidney Symptoms: nephritis Target Organs: Liver Symptoms: Damage

Dihydrostreptomycin sulphate:

General Information : Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting,

Headache, hypotension

SECTION 12: Ecological information

12.1 Toxicity

Components:

Paraffin oil:

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



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Toxicity to fish : LL50 (Scophthalmus maximus (turbot)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Acartia tonsa (Calanoid copepod)): > 100 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Benzylpenicillin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 hrs

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 3.6 mg/l

Exposure time: 48 hrs

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Raphidocelis subcapitata (freshwater green alga)): >

100 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 50

mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

EC50 (blue-green algae): 0.74 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

NOEC (blue-green algae): 0.14 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

icity)

: 1

Toxicity to microorganisms : EC50 : > 500 mg/l

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



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Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 5 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

12.2 Persistence and degradability

Components:

Benzylpenicillin:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 70.10 % Exposure time: 28 d

Method: OECD Test Guideline 301B

12.3 Bioaccumulative potential

Components:

Paraffin oil:

Partition coefficient: n- : log Pow: > 4

octanol/water Remarks: Calculation

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

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



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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

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
IATA : 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
IATA : 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
IATA : 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

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



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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 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.

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 3

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 Parliament and the Council concerning the export and import

of dangerous chemicals

: Not applicable

Not applicable

REACH - List of substances subject to authorisation :

(Annex XIV)

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

Not applicable

Other regulations:

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

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



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

DSL : not determined

AICS : 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 H-Statements

H304 : May be fatal if swallowed and enters airways.

H317 : May cause an allergic skin reaction.

H334 : May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H400 : Very toxic to aquatic life.

H412 : Harmful to aquatic life with long lasting effects.
H413 : May cause long lasting harmful effects to aquatic life.

Full text of other abbreviations

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

Asp. Tox. : Aspiration hazard Resp. Sens. : Respiratory sensitisation Skin Sens. : Skin sensitisation

STOT RE : Specific target organ toxicity - repeated exposure

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : 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

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



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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; 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 compile the Safety Data
Sheet

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

Classification of the mixture:

Calculation method Calculation method Calculation method Calculation method

Asp. Tox. 1
Aquatic Chronic 4

Resp. Sens. 1

Skin Sens. 1

STOT RE 2

H304 H413

H334

H317

H373

Calculation method

Classification procedure:

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