

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

Version 6.0 Revision Date: 14.04.2025 SDS Number: 2456201-00009 Date of last issue: 28.09.2024
Date of first issue: 13.02.2018

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

1.1 Product identifier

Trade name : Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Balıkhisar Mah. Köyiçi Küme Evleri No: 765/A
Çubuk Yolu 2. Km
Akyurt / Ankara / TÜRKİYE

Telephone : +90 312 840 53 00

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

National Poison Control Center (UZEM): 114
Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848 and subsequent amendments

Eye irritation, Category 2	H319: Causes serious eye irritation.
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.
Reproductive toxicity, Category 1A	H360D: May damage the unborn child.
Specific target organ toxicity - single exposure, Category 2	H371: May cause damage to organs.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.

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Short-term (acute) aquatic hazard, Category 1 H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1 H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling T.R. SEA No 28848 and subsequent amendments

Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360D May damage the unborn child.
H371 May cause damage to organs.
H372 Causes damage to organs through prolonged or repeated exposure.
H410 Very toxic 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 protection/ face protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Benzylpenicillin

Streptomycin sulphate

Procaine hydrochloride

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 3 %

2.3 Other hazards

None known.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. KKDIK Registration No.	SEA Classification	Concentration (% w/w)
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
Streptomycin sulphate	3810-74-0 223-286-0	Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317 Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 100	>= 10 - < 20
Procaine hydrochloride	51-05-8 200-077-2	Acute Tox. 3; H301 Eye Irrit. 2; H319 Skin Sens. 1; H317 Repr. 1A; H360D STOT SE 1; H370 (Nervous system, Heart)	>= 1 - < 10

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Piroxicam	36322-90-4 252-974-3	Acute Tox. 3; H301 Repr. 2; H361 STOT RE 1; H372 (Gastrointestinal tract)	>= 1 - < 3
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For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

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.

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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
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 : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). May cause an allergic skin reaction.

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Causes serious eye irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage the unborn child.
May cause damage to organs.
Causes damage to organs through prolonged or repeated exposure.

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 products : Carbon oxides
Nitrogen oxides (NO_x)
Sulphur oxides
Oxides of phosphorus
Metal oxides

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 methods : Use extinguishing measures that are appropriate to local circumstances 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.

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Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. 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 absorbent. 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 determine 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 : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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 mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease,

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should consult their physician regarding working with respiratory irritants or sensitizers.

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 of exposure)	Control parameters	Basis
Benzylpenicillin	61-33-6	TWA	600 µg/m ³ (OEB 2)	Internal
	Further information: RSEN, DSEN			
Streptomycin sulphate	3810-74-0	Wipe limit	100 µg/100 cm ²	Internal
	OEB 2 (>= 100 < 1,000 µg/m ³)			
	Further information: DSEN			
Procaine hydrochloride	51-05-8	TWA	60 µg/m ³ (OEB 3)	Internal
	Wipe limit			
	600 µg/100 cm ²			
Piroxicam	36322-90-4	TWA	100 µg/m ³ (OEB 2)	Internal

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Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Potassium dihydrogenorthophosphate	Workers	Inhalation	Long-term systemic effects	14,82 mg/m3
	Consumers	Inhalation	Long-term systemic effects	6,35 mg/m3
	Consumers	Ingestion	Long-term systemic effects	70 mg/kg bw/day
Dipotassium hydrogenorthophosphate	Workers	Inhalation	Long-term systemic effects	19,1 mg/m3
	Consumers	Inhalation	Long-term systemic effects	8,17 mg/m3
	Consumers	Ingestion	Long-term systemic effects	70 mg/kg bw/day
Potassium dihydrogenorthophosphate	Workers	Inhalation	Long-term systemic effects	14,82 mg/m3
	Consumers	Inhalation	Long-term systemic effects	6,35 mg/m3
	Consumers	Ingestion	Long-term systemic effects	70 mg/kg bw/day
Dipotassium hydrogenorthophosphate	Workers	Inhalation	Long-term systemic effects	19,1 mg/m3
	Consumers	Inhalation	Long-term systemic effects	8,17 mg/m3
	Consumers	Ingestion	Long-term systemic effects	70 mg/kg bw/day

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Benzylpenicillin	Water	0,014 mg/l

8.2 Exposure controls

Engineering measures

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

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.

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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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to TS EN 143
Filter type	: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: liquid
Colour	: No data available
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: 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
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	

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Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Molecular weight : No data available
Particle size : Not applicable

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.

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 toxicological effects

Information on likely routes of : Inhalation
exposure Skin contact

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Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

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

Streptomycin sulphate:

Acute oral toxicity	: LD50 (Hamster): 400 mg/kg
	LD50 (Rat): 430 mg/kg
	LD50 (Mouse): 25.000 mg/kg
Acute toxicity (other routes of administration)	: LD50 (Mouse): 85 - 111 mg/kg Application Route: Intravenous
	LD50 (Mouse): 575 - 610 mg/kg Application Route: Intraperitoneal
	LD50 (Mouse): 500 - 600 mg/kg Application Route: Subcutaneous
	TDLo (Dog): 220 - 440 mg/kg Application Route: Intravenous Symptoms: Lowered blood pressure
	LDLo (Monkey): 110 mg/kg Application Route: Intravenous
	TDLo (Monkey): 30 - 70 mg/kg Application Route: Subcutaneous Symptoms: respiratory depression

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Procaine hydrochloride:

Acute oral toxicity	: LD50 (Rat): 200 mg/kg
	LD50 (Mouse): 350 mg/kg
Acute toxicity (other routes of administration)	: LD50 (Rat): 43 mg/kg Application Route: Intravenous
	LD50 (Mouse): 33 mg/kg Application Route: Intravenous
	LD50 (Dog): 33 mg/kg Application Route: Intravenous

Piroxicam:

Acute oral toxicity	: LD50 (Rat): 216 mg/kg
	LD50 (Dog): 108 mg/kg
	LD50 (Hamster): 170 mg/kg
	LD50 (Guinea pig): 388 mg/kg
	LD50 (Monkey): 1.000 mg/kg
Acute dermal toxicity	: LD50 (Rat): > 5.000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Streptomycin sulphate:

Result	: Mild eye irritation
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Procaine hydrochloride:

Result	: Moderate eye irritation
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Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

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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
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.

Streptomycin sulphate:

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Dermal
Species	:	Humans
Result	:	Weak sensitizer

Procaine hydrochloride:

Exposure routes	:	Dermal
Result	:	Sensitiser
Remarks	:	Based on human experience. Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Benzylpenicillin:

Germ cell mutagenicity- Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.
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Streptomycin sulphate:

Genotoxicity in vitro	:	Test Type: Chromosomal aberration Result: equivocal
Genotoxicity in vivo	:	Test Type: Chromosomal aberration Cell type: Human lymphocytes Result: negative

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Procaine hydrochloride:

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

Piroxicam:

Genotoxicity in vivo : Test Type: sister chromatid exchange assay
Species: Humans
Cell type: Human lymphocytes
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Streptomycin sulphate:

Species : Rat
Application Route : Oral
NOAEL : 5 mg/kg body weight
Result : negative

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Reproductive toxicity

May damage the unborn child.

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 development : Test Type: Development
Species: Mouse
Result: No effects on foetal development

Test Type: Development

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Species: Rat
Result: No effects on foetal development

Test Type: Development
Species: Rabbit
Result: No effects on foetal development

Streptomycin sulphate:

Effects on fertility	: Test Type: Fertility Species: Rat Application Route: Intraperitoneal Fertility: LOAEL: 40 mg/kg body weight Symptoms: male reproductive effects
Effects on foetal development	: Test Type: Development Species: Mouse Application Route: Intraperitoneal Developmental Toxicity: LOAEL: 250 mg/kg body weight Symptoms: fetal deafness, Embryo-foetal toxicity
	: Test Type: Development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: No teratogenic effects
Reproductive toxicity - Assessment	: May damage the unborn child.

Procaine hydrochloride:

Reproductive toxicity - Assessment	: May damage the unborn child.
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Piroxicam:

Effects on foetal development	: Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: Embryo-foetal toxicity, No teratogenic effects, Fetal growth retardation
	: Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 30 mg/kg body weight Symptoms: foetal mortality Result: Embryo-foetal toxicity, No teratogenic effects, Fetal growth retardation Remarks: Maternal toxicity observed.

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Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0,4 - 4 mg/kg body weight
Result: Effects on foetal development

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: No embryo-foetal toxicity

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

STOT - single exposure

May cause damage to organs.

Components:

Procaine hydrochloride:

Target Organs : Nervous system, Heart
Assessment : Causes damage to organs.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

Streptomycin sulphate:

Target Organs : Kidney, inner ear
Assessment : Causes damage to organs through prolonged or repeated exposure.

Piroxicam:

Target Organs : Gastrointestinal tract
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Streptomycin sulphate:

Species : Rat
NOAEL : 100 mg/kg
Application Route : Subcutaneous
Exposure time : 72 Days
Remarks : No significant adverse effects were reported

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Species	:	Cat
LOAEL	:	200 mg/kg
Application Route	:	Oral
Exposure time	:	90 Days
Target Organs	:	inner ear
Species	:	Dog
LOAEL	:	44 mg/kg
Application Route	:	Intramuscular
Exposure time	:	14 Days
Target Organs	:	inner ear
Species	:	Dog
LOAEL	:	50 - 100 mg/kg
Application Route	:	Intramuscular
Exposure time	:	20 Days
Target Organs	:	inner ear, Kidney
Symptoms	:	ataxia
Species	:	Monkey
NOAEL	:	50 mg/kg
LOAEL	:	100 mg/kg
Application Route	:	Intramuscular
Exposure time	:	5 Days
Target Organs	:	Liver, Kidney
Species	:	Rat
NOAEL	:	5 mg/kg
Application Route	:	Oral
Exposure time	:	2 yr
Remarks	:	No significant adverse effects were reported
Species	:	Monkey
LOAEL	:	25 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	66 Days
Target Organs	:	Blood, Liver, Kidney
Symptoms	:	anemia

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Benzylpenicillin:

Inhalation	:	Symptoms: Allergic reactions, Abdominal pain, bronchospasm, skin rash
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Streptomycin sulphate:

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Inhalation	: Target Organs: inner ear Symptoms: hearing loss Target Organs: Kidney Symptoms: hearing loss
Skin contact	: Symptoms: skin rash
Procaine hydrochloride:	
Inhalation	: Target Organs: Central nervous system Symptoms: nervousness, Dizziness, Convulsions, Breathing difficulties, Rash, Swelling of tissue, irregular heart beat Remarks: May cause harm to the unborn child. Based on clinical use Target Organs: Heart Symptoms: nervousness, Dizziness, Convulsions, Breathing difficulties, Rash, Swelling of tissue, irregular heart beat Remarks: May cause harm to the unborn child. Based on clinical use
Piroxicam:	
Ingestion	: Target Organs: Gastrointestinal tract Symptoms: Diarrhoea, constipation, flatulence, Headache, Dizziness, tinnitus, skin rash, Ulceration, chest pain, Abdominal pain

SECTION 12: Ecological information

12.1 Toxicity

Components:

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

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		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 toxicity)	:	1
Toxicity to microorganisms	:	EC50 : > 500 mg/l 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
Streptomycin sulphate:		
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 487 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Microcystis aeruginosa (blue-green algae)): 0,007 mg/l Exposure time: 72 h Method: ISO 8692
		EC50 (Selenastrum capricornutum (green algae)): 0,133 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	100
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 32 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	100
Procaine hydrochloride:		
Ecotoxicology Assessment		
Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded

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II

Piroxicam:

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded
Chronic aquatic toxicity : Toxic effects cannot be excluded

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:

Streptomycin sulphate:

Partition coefficient: n-octanol/water : log Pow: -3,2

Procaine hydrochloride:

Partition coefficient: n-octanol/water : log Pow: 2,14

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
Waste management needs to comply with provisions laid down in Waste Management Regulation (TR Official Gazette, 2015, Number: 29314) and with the respective national provisions legally enforced

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Contaminated packaging

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.

: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN	:	UN 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
IATA	:	UN 3082

14.2 UN proper shipping name

ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin, Streptomycin sulphate)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin, Streptomycin sulphate)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin, Streptomycin sulphate)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin, Streptomycin sulphate)
IATA	:	Environmentally hazardous substance, liquid, n.o.s. (Benzylpenicillin, Streptomycin sulphate)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	:	9
ADR	:	9
RID	:	9

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IMDG : 9

IATA : 9

14.4 Packing group

ADN

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

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Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : 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.

Regulation on Persistent Organic Pollutants (Number 30595 and subsequent amendments published) : Not applicable

Regulation on prevention of major industrial accidents. Reg number 30702

E1

ENVIRONMENTAL
HAZARDS

Quantity 1

100 t

Quantity 2

200 t

Other regulations:

T.R. Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated December 11, 2013 and numbered 28848 from the Ministry of Environment and Urbanization and the subsequent amendments published.

Regulation on Import and Export of Certain Hazardous Chemicals, No. 32087, 2023 : Not applicable

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
The SDS has been prepared by: Name: Gökhan Ardiç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025

Full text of H-Statements

H301 : Toxic if swallowed.
H302 : Harmful if swallowed.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360D : May damage the unborn child.
H361 : Suspected of damaging fertility or the unborn child.
H370 : Causes damage to organs.
H372 : Causes damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
H412 : Harmful to aquatic life with long lasting effects.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Resp. Sens. : Respiratory sensitisation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure

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STOT SE : Specific target organ toxicity - single exposure

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; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to 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:

Eye Irrit. 2	H319
Resp. Sens. 1	H334
Skin Sens. 1	H317
Repr. 1A	H360D
STOT SE 2	H371
STOT RE 1	H372

Classification procedure:

Calculation method

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Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

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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.

TR / EN