

Version 6.4	Revision Date: 28.09.2024	SDS Number: 2456205-00025	Date of last issue: 06.04.2024 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 Hydrochlo- ride / Piroxicam Liquid Formulation
1.2 Relevant identified uses of the	e si	ubstance or mixture and uses advised against
Use of the Sub- stance/Mixture		Veterinary product
Recommended restrictions on use	:	Not applicable
1.3 Details of the supplier of the s	safe	ety data sheet
Company	:	MSD Kilsheelan Clonmel Tipperary, IE
Telephone	:	353-51-601000
E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com
1.4 Emergency telephone number	er	

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2 Respiratory sensitisation, Category 1	H319: Causes serious eye irritation. H334: May cause allergy or asthma symptoms or
reconnection, category r	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 pro- longed or repeated exposure.
Short-term (acute) aquatic hazard, Cate- gory 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Cat-	H410: Very toxic to aquatic life with long lasting

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



Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

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	egory 1			effects	
2.2 L	.abel el	ements			
	Labelling (REGULATION (E Hazard pictograms		C) I :	No 1272/2008)	
	Signal	word	:	Danger	
	Hazard	statements	:	H319 Causes se H334 May cause difficulties if inhale H360D May dama H371 May cause H372 Causes da peated exposure.	e an allergic skin reaction. rious eye irritation. e allergy or asthma symptoms or breathing d. ge the unborn child. e damage to organs. mage to organs through prolonged or re- to aquatic life with long lasting effects.
	Precautionary statements		:	P273 Avoid relea	ecial instructions before use. ase to the environment. active gloves/ protective clothing/ eye protec- n.
				P304 + P340 IF keep comfortable f	experiencing respiratory symptoms: Call a / doctor.
	Hazard	ous components whicl	h m	ust be listed on the	label:

Benzylpenicillin Streptomycin sulphate Procaine hydrochloride

Additional Labelling

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

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.



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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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	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	>= 10 - < 20
		M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 100	
Procaine hydrochloride	51-05-8 200-077-2	Acute Tox. 3; H301 Eye Irrit. 2; H319 Skin Sens. 1; H317	>= 1 - < 10



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Pirox	icam	36322-90-4 252-974-3	Repr. 1A; H360D STOT SE 1; H370 (Nervous system, Heart) Acute Tox. 3; H301 Repr. 2; H361 STOT RE 1; H372 (Gastrointestinal tract)	>= 1 - < 3		

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.
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 : May cause an allergic skin reaction.



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			Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficul- ties if inhaled. May damage the unborn child. May cause damage to organs. Causes damage to organs through prolonged or repeated exposure.				
			other respiratory	sure may aggravate preexisting asthma and y disorders (e.g. emphysema, bronchitis, reac- function syndrome).			
4.3 Indica	ation of any immediate	me	dical attention a	nd special treatment needed			
Trea	tment	:	Treat symptoma	atically and supportively.			
	N 5: Firefighting mea	sur	es				
	guishing media						
Suita	ble extinguishing media	:	Water spray Alcohol-resistan Carbon dioxide Dry chemical				
Unsu medi	uitable extinguishing a	:	None known.				
5.2 Speci	al hazards arising from	n the	e substance or n	nixture			
-	cific hazards during fire-			nbustion products may be a hazard to health.			
Haza ucts	ardous combustion prod-	:	Carbon oxides Nitrogen oxides Sulphur oxides Oxides of phosp Metal oxides				
5.3 Advic	e for firefighters						
Spec	cial protective equipment refighters	:		ire, wear self-contained breathing apparatus. otective equipment.			
Spec ods	ific extinguishing meth-	:	cumstances and Use water spray	ng measures that are appropriate to local cir- d the surrounding environment. y to cool unopened containers. aged containers from fire area if it is safe to do			



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SECTIO	N 6: Accidental relea	ise measures			
6.1 Perso	nal precautions, prote	ective equipment a	nd emergency procedures		
Personal precautions		Follow safe ha	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).		
6.2 Envir	onmental precautions				
Environmental precautions		Prevent furthe Prevent sprea barriers). Retain and dis Local authorit	Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil		
6.3 Metho	ods and material for co	ontainment and cle	aning up		
Methods for cleaning up		For large spill ment to keep be pumped, s Clean up rem bent. Local or natio posal of this n employed in th mine which re Sections 13 a	inert absorbent material. s, provide dyking or other appropriate contain- material from spreading. If dyked material can tore recovered material in appropriate container. aining materials from spill with suitable absor- nal regulations may apply to releases and dis- naterial, as well as those materials and items ne cleanup of releases. You will need to deter- gulations are applicable. nd 15 of this SDS provide information regarding		

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

certain local or national requirements.

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Hygiene measures		 sessment Keep contain Already sens to asthma, all should consultory irritants of Do not eat, d Take care to environment. If exposure to flushing system 	 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 respiratory 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. 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 Cond	itions for safe storage,	, including any inc	compatibilities		
	irements for storage s and containers		erly labelled containers. Store locked up. Keep . Store in accordance with the particular national		
Advi	ce on common storage	Strong oxidiz	substances and mixtures		
7.3 Specific end use(s) Specific use(s)		: No data avail	able		

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/m3 (OEB 2)	Internal				
	Further inform	Further information: RSEN, DSEN						
		Wipe limit	100 µg/100 cm2	Internal				
Streptomycin sul- phate	3810-74-0	TWA	OEB 2 (>= 100 < 1,000 µg/m3)	Internal				



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		Further inform	mation: DSEN			
	Procaine hydro- chloride	51-05-8	TWA	60 µg/m3 (OEB 3)	Internal	
			Wipe limit	600 μg/100 cm ²	Internal	
	Piroxicam	36322-90-4	TWA	100 μg/m3 (OEB 2)	Internal	

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

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Potassium dihy- drogenorthophos- phate	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 hy- drogenorthophos- phate	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) according to Regulation (EC) No. 1907/2006

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. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection Material	:	Chemical-resistant gloves
Skin and body protection Respiratory protection	:	Work uniform or laboratory coat. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec-



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Filter type		0	delines, use respiratory protection. uld conform to NS EN 143 ve (P)
SECTION	0. Physical and c	hemical properties	

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
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)	:	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
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
рН	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n- octanol/water	:	Not applicable



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Vapour pressure		:	No data available	e					
F	Relative density		:	: No data available					
C	Density		:	: No data available					
F	Relative vapour density		:	No data available	e				
F	Particle characteristics Particle size		:	Not applicable					
9.2 O	ther in	nformation							
E	Explos	ives	:	Not explosive					
C	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.				
E	Evapor	ration rate	:	No data available	e				
Ν	Molecu	ılar weight	:	No data available	e				

SECTION 10: Stability and reactivity

10.1 Reactivity Not classified as a reactivity hazard. 10.2 Chemical stability Stable under normal conditions. 10.3 Possibility of hazardous reactions Hazardous reactions : 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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of	:	Inhalation
exposure		Skin contact



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				Ingestion Eye contact			
		toxicity ssified based on availa	ble	information.			
	Produc	<u>ct:</u>					
	Acute oral toxicity :		:	Acute toxicity estimate: > 2.000 mg/kg Method: Calculation method			
	Compo	onents:					
	Benzyl	penicillin:					
	Acute o	oral toxicity	:	LD50 (Rat): 8.000	mg/kg		
				LD50 (Mouse): >	5.000 mg/kg		
		oxicity (other routes of stration)	:	LD50 (Mouse): 3.9 Application Route			
				LD50 (Mouse): 32 Application Route			
	Strepto	omycin sulphate:					
	Acute o	oral toxicity	:	LD50 (Hamster): 4	400 mg/kg		
				LD50 (Rat): 430 m	ng/kg		
				LD50 (Mouse): 25	5.000 mg/kg		
		oxicity (other routes of stration)	:	LD50 (Mouse): 85 Application Route			
				LD50 (Mouse): 57 Application Route			
				LD50 (Mouse): 50 Application Route			
				TDLo (Dog): 220 - Application Route Symptoms: Lower			
				LDLo (Monkey): 1 Application Route			
				TDLo (Monkey): 3 Application Route Symptoms: respire	: Subcutaneous		



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	aine hydrochloride:			
Acut	e oral toxicity	:	LD50 (Rat): 200 n	ng/kg
			LD50 (Mouse): 35	50 mg/kg
	e toxicity (other routes of inistration)	:	LD50 (Rat): 43 mg Application Route	
			LD50 (Mouse): 33 Application Route	
			LD50 (Dog): 33 m Application Route	
Piro	xicam:			
Acut	e oral toxicity	:	LD50 (Rat): 216 n	ng/kg
			LD50 (Dog): 108 i	mg/kg
			LD50 (Hamster):	170 mg/kg
			LD50 (Guinea pig): 388 mg/kg
			LD50 (Monkey): 1	.000 mg/kg
Acut	e dermal toxicity	:	LD50 (Rat): > 5.00	00 mg/kg
Skin	corrosion/irritation			
	classified based on availa			
	ous eye damage/eye irr ses serious eye irritation.	itati	on	
Com	ponents:			
Stre Resu	ptomycin sulphate: ult	:	Mild eye irritation	
Proc Resu	caine hydrochloride: ult	:	Moderate eye irrit	ation
Res	piratory or skin sensitis	satio	on	
-	sensitisation cause an allergic skin re	actio	on.	



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Re	spiratory sensitisation						
Ma	ay cause allergy or asthma	sympt	oms or breathing	difficulties if inhaled.			
<u>Co</u>	emponents:						
Ве	nzylpenicillin:						
	st Type		ocal lymph node	assay (LLNA)			
	posure routes		Dermal				
	ecies sult		louse Veak sensitizer				
Te	st Type	: N	laximisation Test	t			
	posure routes		Dermal				
	ecies		Guinea pig				
	esult emarks		ositive Based on data fro	m similar materials			
-	sult		Strong sensitizer				
Re	marks	: 6	Based on human	experience.			
Sti	reptomycin sulphate:						
	st Type		•	ult patch test (HRIPT)			
	posure routes		Dermal				
	ecies sult		lumans Veak sensitizer				
	out	. •					
	ocaine hydrochloride:						
	posure routes		Dermal				
-	sult		Sensitiser				
Re	marks		: Based on human experience. Based on data from similar materials				
	rm cell mutagenicity t classified based on availa	ble in	formation				
	mponents:		ionnation.				
	nzylpenicillin:						
	erm cell mutagenicity- As-		Veight of evidenc ell mutagen.	e does not support classification as a germ			
			C				
	reptomycin sulphate:						
Ge	enotoxicity in vitro		est Type: Chrom Result: equivocal	osomal aberration			
Ge	enotoxicity in vivo			osomal aberration			
			Cell type: Human Result: negative	lymphocytes			
			_				
			13/26				



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	-	:	Test Type: Bacter Result: equivocal	ial reverse mutation assay (AMES)
		:	Test Type: sister of Species: Humans Cell type: Human Result: negative	chromatid exchange assay lymphocytes
		ble	information.	
Compo	nents:			
Species Applicat NOAEL	tion Route	:	Rat Oral 5 mg/kg body weig negative	ght
	genicity - Assess-	:	Weight of evidenc cinogen	e does not support classification as a car-
May da	mage the unborn child.			
Benzyl	penicillin:			
Effects	on fertility	:	Test Type: Fertility Species: Mouse Result: No effects	
			Test Type: Fertility Species: Rat Result: No effects	
			Test Type: Fertility Species: Rabbit Result: No effects	
	on foetal develop-	:	Test Type: Develo Species: Mouse Result: No effects Test Type: Develo	on foetal development
	Genoto: Piroxic Genoto: Carcino Not clas <u>Compo</u> Species Applicat NOAEL Result Carcino ment Reprod May dat <u>Compo</u> Benzyli Effects	28.09.2024 Procaine hydrochloride: Genotoxicity in vitro Piroxicam: Genotoxicity in vivo Carcinogenicity Not classified based on availa <u>Components:</u> Streptomycin sulphate: Species Application Route NOAEL Result Carcinogenicity - Assess- ment Reproductive toxicity May damage the unborn child <u>Components:</u> Benzylpenicillin: Effects on fertility Effects on foetal develop-	28.09.2024 24 Procaine hydrochloride: Genotoxicity in vitro : Genotoxicity in vitro : Piroxicam: Genotoxicity in vivo : Genotoxicity in vivo : : Piroxicam: Genotoxicity in vivo : Carcinogenicity Not classified based on available : Components: Streptomycin sulphate: : Species : : Application Route : : NOAEL : : Result : : Carcinogenicity - Assess- : : May damage the unborn child. : : Components: Benzylpenicillin: : Effects on fertility : :	28.09.2024 2456205-00025 Procaine hydrochloride: Genotoxicity in vitro : Test Type: Bacter Result: equivocal Piroxicam: Genotoxicity in vitro : Test Type: sister of Species: Humans Cell type: Human Result: negative Carcinogenicity Not classified based on available information. Components: Streptomycin sulphate: Species : Rat Application Route : Oral NOAEL : 5 mg/kg body weig Result : negative Carcinogenicity - Assess- : Weight of evidence cinogen Reproductive toxicity May damage the unborn child. Components: Benzylpenicillin: Effects on fertility : Test Type: Fertility Species: Rat Result: No effects Test Type: Fertility : Test Type: Fertility Species: Rat Result: No effects Effects on foetal develop-ment : Test Type: Develop Ment : Species: Rabbit Result: No effects



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			Test Type: Develo Species: Rabbit	on foetal development opment on foetal development
Str	eptomycin sulphate:			
	ects on fertility	:		
Effe mei	ects on foetal develop- nt	:		
			Test Type: Develor Species: Rabbit Application Route Developmental To Result: No teratog	: Oral xicity: NOAEL: 10 mg/kg body weight
•	productive toxicity - As- sment	:	May damage the u	unborn child.
Pro	caine hydrochloride:			
•	productive toxicity - As- sment	:	May damage the u	unborn child.
Pire	oxicam:			
Effe mei	ects on foetal develop- nt	:		: Oral xicity: LOAEL: 10 mg/kg body weight etal toxicity, No teratogenic effects, Fetal
			Symptoms: foetal Result: Embryo-fo growth retardation	oral exicity: LOAEL: 30 mg/kg body weight mortality etal toxicity, No teratogenic effects, Fetal



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			Result: Effects or Test Type: Development Species: Rabbit Application Route	e: Oral oxicity: LOAEL: 0,4 - 4 mg/kg body weight n foetal development opment e: Oral oxicity: NOAEL: 10 mg/kg body weight
	roductive toxicity - As-	:	Suspected of dan	naging the unborn child.
STC)T - single exposure			
May	cause damage to organ	s.		
<u>Con</u>	nponents:			
	caine hydrochloride:			
	jet Organs essment	:	Nervous system, Causes damage	
Cau <u>Con</u>	OT - repeated exposure ses damage to organs the apponents:	nroug	h prolonged or rep	peated exposure.
	ptomycin sulphate:			
	get Organs essment	:	Kidney, inner ear Causes damage exposure.	to organs through prolonged or repeated
Piro	xicam:			
	get Organs essment	:	Gastrointestinal to Causes damage exposure.	ract to organs through prolonged or repeated
Rep	eated dose toxicity			
<u>Con</u>	nponents:			
Stre	ptomycin sulphate:			
Spe	cies	:	Rat	
NO/ App	AEL lication Route	:	100 mg/kg Subcutaneous	
Exp	osure time	:	72 Days	
Ren	narks		No significant adv	verse effects were reported



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Speci	es	: Cat	
LOAE		: 200 mg/kg	
	cation Route	: Oral	
	sure time	: 90 Days	
	et Organs	: inner ear	
Speci		: Dog	
LOAE		: 44 mg/kg	
	cation Route	: Intramuscular	
•	sure time	: 14 Days	
Targe	et Organs	: inner ear	
Speci		: Dog	
LOAE		: 50 - 100 mg/kg	
	cation Route	: Intramuscular	
	sure time	: 20 Days	
	et Organs	: inner ear, Kidne	Y
Symp	toms	: ataxia	
Speci	es	: Monkey	
NOAE		: 50 mg/kg	
LOAE		: 100 mg/kg	
	cation Route	: Intramuscular	
	sure time	: 5 Days	
Targe	et Organs	: Liver, Kidney	
Speci		: Rat	
NOAE		: 5 mg/kg	
	cation Route	: Oral	
•	sure time	: 2 yr	
Rema	arks	: No significant a	dverse effects were reported
Speci		: Monkey	
LOAE		: 25 mg/kg	
	cation Route	: Subcutaneous	
	sure time	: 66 Days	
	t Organs	: Blood, Liver, Kid	dney
Symp	toms	: anemia	

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation



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				(EU) 2017/2100 o levels of 0.1% or h	r Commission Regulation (EU) 2018/605 at nigher.
E	xperien	ce with human exp	osu	re	
<u>C</u>	ompone	ents:			
	enzylpe halation	enicillin:	:	Symptoms: Allerg chospasm, skin ra	ic reactions, Abdominal pain, bron-
	treptom halation	nycin sulphate:	:	Target Organs: in Symptoms: hearin Target Organs: Ki	ner ear ig loss
SI	kin cont	act	:	Symptoms: hearin Symptoms: skin ra	
Рі	rocaine	hydrochloride:			
In	halation	1	:	Symptoms: nervoi difficulties, Rash, Remarks: May car Based on clinical Target Organs: He Symptoms: nervoi difficulties, Rash,	eart usness, Dizziness, Convulsions, Breathing Swelling of tissue, irregular heart beat use harm to the unborn child.
Pi	iroxicar	n:			
In	ngestion		:	Symptoms: Diarrh	astrointestinal tract oea, constipation, flatulence, Headache, , skin rash, Ulceration, chest pain, Ab-

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



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	Toxicity to algae/aquatic plants		:	EC50 (Raphidoce 100 mg/l Exposure time: 72 Method: OECD Te	
				NOEC (Raphidoco mg/l Exposure time: 72 Method: OECD Te	
				EC50 (blue-green Exposure time: 72 Method: OECD Te	2 hrs
				NOEC (blue-green Exposure time: 72 Method: OECD Te	
	M-Facto icity)	or (Acute aquatic tox-	:	1	
	Toxicity	v to microorganisms	:	EC50 : > 500 mg/ Exposure time: 3 Test Type: Respir Method: OECD Te	h ation inhibition
				NOEC : 5 mg/l Exposure time: 3 l Test Type: Respir Method: OECD Te	ation inhibition
	Strepto	omycin sulphate:			
	Toxicity	to daphnia and other invertebrates	:	EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
	Toxicity plants	to algae/aquatic	:	EC50 (Microcystis Exposure time: 72 Method: ISO 8692	
				EC50 (Selenastru Exposure time: 72 Method: OECD Te	
	M-Facto icity)	or (Acute aquatic tox-	:	100	
		v to daphnia and other invertebrates (Chron-	:	NOEC: 32 mg/l Exposure time: 21	d



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ic	toxicity)	Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211	
	1-Factor (Chronic aquatic oxicity)	: 100	
Р	rocaine hydrochloride:		
	cotoxicology Assessm	ent : Toxic effects cannot be excluded	
С	hronic aquatic toxicity	: Toxic effects cannot be excluded	
Р	iroxicam:		
	cotoxicology Assessm	ent : Toxic effects cannot be excluded	
С	hronic aquatic toxicity	: Toxic effects cannot be excluded	
12.2 P	Persistence and degrad	bility	
<u>c</u>	components:		
	e nzylpenicillin: iodegradability	 Result: Readily biodegradable. Biodegradation: 70,10 % Exposure time: 28 d Method: OECD Test Guideline 301B 	
12.3 B	Bioaccumulative potent	al	
<u>C</u>	components:		
Р	treptomycin sulphate: artition coefficient: n- ctanol/water	: log Pow: -3,2	
Р	rocaine hydrochloride: artition coefficient: n- ctanol/water	: log Pow: 2,14	
	lobility in soil lo data available		
12.5 R	Results of PBT and vPvI	assessment	
P	roduct:		
	ssessment	: This substance/mixture contains no components consider to be either persistent, bioaccumulative and toxic (PBT), or	



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		very persistent a 0.1% or higher.	nd very bioaccumulative (vPvB) at levels of
12.6 Endo	crine disrupting prop	erties	
<u>Produ</u>	<u>ict:</u>		
Assessment		ered to have end REACH Article 5	hixture does not contain components consid- docrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.
	adverse effects		

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	 Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	 Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	:	UN 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
ΙΑΤΑ	:	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.



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			(Benzylpenicillin, Streptomycin sulphate)	
RID		:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin, Streptomycin sulphate)	
IMD	G	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin, Streptomycin sulphate)	
IAT	A	:	Environmentally hazardous substance, liquid, n.o.s. (Benzylpenicillin, Streptomycin sulphate)	
14.3 Tra	nsport hazard class(es)			
			Class Subsidiary risks	
ADN	N	:	9	
ADF	R	:	9	
RID		:	9	
IMD	G	:	9	
IAT	Α	:	9	
14.4 Pac	king group			
Clas Haz Labo Pac Clas Haz Labo	king group ssification Code ard Identification Number els R king group ssification Code ard Identification Number		III M6 90 9 9 III M6 90 9 9 (-)	
Clas	king group ssification Code ard Identification Number	: : :	III M6 90 9	
Lab	king group	:	III 9 F-A, S-F	
Pac airci Pac	A (Cargo) king instruction (cargo raft) king instruction (LQ) king group	:	964 Y964 III	



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	Labels		:	Miscellaneous	
	Packin	Passenger) g instruction (passen-	:	964	
		craft) g instruction (LQ) g group	:	Y964 III	
	Labels		:	Miscellaneous	
14.5 Environmental hazards					
	ADN Enviror	nmentally hazardous	:	yes	
	ADR Enviroi	nmentally hazardous	:	yes	
	RID Enviroi	nmentally hazardous	:	yes	
	IMDG Marine	pollutant	:	yes	
		Passenger) nmentally hazardous	:	yes	
	•	Cargo) nmentally hazardous	:	ves	
446		al processions for use			

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.

: Not applicable for product as supplied.

14.7 Maritime transport in bulk according to IMO instruments

Remarks

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 appli-

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



Benzylpenicillin / Streptomycin Sulphate / Procaine Hydrochloride / Piroxicam Liquid Formulation

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						cable to the placing	on the market or
						not.	
		 Candidate List of Sunning of for Authorisation (Art 	ibstances of Very High icle 59).		:	Not applicable	
R		- List of substances s	ubject to authorisation		:	Not applicable	
-	egulati yer	on (EC) on substance	es that deplete the ozor	ne	:	Not applicable	
	egulati nts (re		n persistent organic po	llu-	:	Not applicable	
Re me	egulati ent an	on (EU) No 649/2012	of the European Parlia ing the export and imp		:	Not applicable	
Se	eveso	III: Directive 2012/18/I	EU of the European Pa ing dangerous substar		ent	and of the Council or	n the control of
	•					Quantity 1	Quantity 2

		Quantity	Quantity Z
E1	ENVIRONMENTAL	100 t	200 t
	HAZARDS		

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

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

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 difficul-



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H360[H361 H370 H372 H400 H410 H412)		Causes damage Causes damage exposure. Very toxic to aqua Very toxic to aqua	naging fertility or the unborn child. to organs. to organs through prolonged or repeated
Full te	ext of other abbreviati	ons		
Aquati Eye Ir Repr.	ic Acute ic Chronic rit. Sens. Sens. RE		Eye irritation Reproductive toxi Respiratory sensi Skin sensitisation Specific target or	ic) aquatic hazard city tisation

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 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



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- United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture	Classification procedure:	
Eye Irrit. 2	H319	Calculation method
Resp. Sens. 1	H334	Calculation method
Skin Sens. 1	H317	Calculation method
Repr. 1A	H360D	Calculation method
STOT SE 2	H371	Calculation method
STOT RE 1	H372	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	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