

Cefuroxime Formulation

Vers 2.3	sion	Revision Date: 30.11.2023		DS Number: 844545-00005	Date of last issue: 30.09.2023 Date of first issue: 06.09.2022
SEC	CTION	1: Identification of t	he	substance/mixt	ure and of the company/undertaking
1.1 F	Product	t identifier			
	Trade r	name	:	Cefuroxime Form	ulation
Other means of identification		:	Spectrazol Milking Cow (A005270) Coopers Cepravin LC Lactating Cow Intramammary Antibiotic (47941)		
1.2 F	Relevar	nt identified uses of th	ne s	substance or mixt	ure and uses advised against
Use of the Sub- stance/Mixture Recommended restrictions on use		:	Veterinary produc	t	
		:	Not applicable		
1.3 [Details	of the supplier of the	saf	ety data sheet	
Company		:	MSD 20 Spartan Road 1619 Spartan, So	outh Africa	
Telephone		:	+27119239300		
E-mail address of person : responsible for the SDS		:	EHSDATASTEW	ARD@msd.com	
1.4 E	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.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word	:
Hazard statements	:

: H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



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Preca	utionary statements	keep comfortable	experiencing respiratory symptoms: Call a

Hazardous components which must be listed on the label:

Cefuroxime

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 8,33 %

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)
Cefuroxime	Registration number 55268-75-2 259-560-1	Resp. Sens. 1; H334 STOT RE 2; H373	>= 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.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water.



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			Get medical atter	ntion if symptoms occur.		
In cas	se of eye contact	:		vater as a precaution. ntion if irritation develops and persists.		
If swallowed		:	: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.			
4.2 Most i	mportant symptoms a	nd e	effects, both acut	e and delayed		
Risks		:	May cause allerg ties if inhaled.	y or asthma symptoms or breathing difficul-		
			other respiratory	ure may aggravate preexisting asthma and disorders (e.g. emphysema, bronchitis, readunction syndrome).		
	•	meo		d special treatment needed		
Treat	ment	:	Treat symptomat	ically and supportively.		
5.1 Exting	V 5: Firefighting mean puishing media ble extinguishing media	sur :	es Water spray			
5.1 Exting Suital Unsui	Juishing media ble extinguishing media itable extinguishing	sur : :				
5.1 Exting Suital	Juishing media ble extinguishing media itable extinguishing	sur :	Water spray Alcohol-resistant Carbon dioxide (Dry chemical			
5.1 Exting Suital Unsui media 5.2 Specia	Juishing media ble extinguishing media itable extinguishing a al hazards arising from	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical None known.	CO2) ixture		
5.1 Exting Suital Unsui media 5.2 Specia	Juishing media ble extinguishing media itable extinguishing a a hazards arising from	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical None known.	CO2) ixture		
5.1 Exting Suital Unsui media 5.2 Specia Speci fightir	Juishing media ble extinguishing media itable extinguishing a a hazards arising from	:	Water spray Alcohol-resistant Carbon dioxide (Dry chemical None known.	CO2) ixture bustion products may be a hazard to health		
 5.1 Exting Suital Unsui media 5.2 Specia Speci fightir Hazar ucts 	uishing media ble extinguishing media itable extinguishing a al hazards arising from ific hazards during fire-	: : : :	Water spray Alcohol-resistant Carbon dioxide (Dry chemical None known. e substance or m Exposure to com Carbon oxides Nitrogen oxides (CO2) ixture bustion products may be a hazard to health		
 5.1 Exting Suital Unsui media 5.2 Specia Speci fightir Hazau ucts 5.3 Advice Speci 	Juishing media ble extinguishing media itable extinguishing a al hazards arising from fic hazards during fire- ng rdous combustion prod-	: : :	Water spray Alcohol-resistant Carbon dioxide (Dry chemical None known. e substance or m Exposure to com Carbon oxides Nitrogen oxides (Sulphur oxides	CO2) ixture bustion products may be a hazard to health		



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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 protective equipment recommendations (see section 8). 6.2 Environmental precautions Avoid release to the environment

Environmental precaution	s :	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

F F C C C C C C C C C C C C C C C C C C	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate contain- ment 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 dis- bosal 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.
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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 Advice on safe handling	::	Use only with adequate ventilation.
		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.



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Hygiene measures		en : If e flu: pla na Th en ap	Take care to prevent spills, waste and minimize release to th environment. If exposure to chemical is likely during typical use, provide ey flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contam nated 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	
7.2 Con	ditions for safe storage,	includi	n <mark>g any inco</mark> m	patibilities
Requirements for storage areas and containers			Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.	
Adv	vice on common storage		o not store with rong oxidizing	the following product types: agents

Gases

7.3 Specific end use(s)

Specific use(s)	: No data available
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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	
Cefuroxime	55268-75-2	TWA	100 µg/m3 (OEB 2)	Internal	
	Further information: RSEN				

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

Substance name	Environmental Compartment	Value
Glycerides, mixed C8-10 and succinyl	Fresh water	0,0017 mg/l
	Freshwater - intermittent	0,676 mg/l
	Marine water	0,00017 mg/l
	Sewage treatment plant	4,55 mg/kg dry weight (d.w.)
	Fresh water sediment	390,49 mg/kg dry weight (d.w.)
	Marine sediment	39,05 mg/kg dry weight (d.w.)
	Soil	78,01 mg/kg dry weight (d.w.)



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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- ommended guidelines, use respiratory protection.
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

internation on sacre phycical		a ononnoai proporti
Appearance Colour	:	liquid white off-white
Odour Odour Threshold	:	No data available No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available
range Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
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



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Relative density		: No data available	
Dens	ity	: No data available	
W Partit octan Auto-	ility(ies) ater solubility ion coefficient: n- ol/water ignition temperature mposition temperature	 No data available Not applicable No data available No data available 	
Visco Vis	sity scosity, kinematic	: No data available	
Explo	sive properties	: Not explosive	
Oxidiz	zing properties	: The substance or mixture is not classified as oxidizir	ıg.
Flam	information mability (liquids) cular weight cle size	 No data available No data available Not applicable 	
Moleo	cular weight		

SECTION 10: Stability and reactivity

10.1 Reactivity Not classified as a reactivity haza	rd.			
10.2 Chemical stability Stable under normal conditions.				
10.3 Possibility of hazardous reaction	ons			
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.				



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.1 Inforn	11: Toxicological in nation on toxicologica ation on likely routes of		mation	
. 1 Inforn Inform	nation on toxicologica ation on likely routes of			
Inform	ation on likely routes of	l ef		
	•			
	110		Inhalation Skin contact Ingestion Eye contact	
	toxicity			
	assified based on availa onents:	bie	information.	
Cefuro Acute	oral toxicity	:	LD50 (Rat): > 10	0.000 mg/kg
			LD50 (Mouse): :	> 10.000 mg/kg
	toxicity (other routes of stration)	:	LD50 (Rat): > 4. Application Rou	
			LD50 (Mouse): : Application Rou	
			LD50 (Rabbit): > Application Rou	
			LD50 (Dog): > 1 Application Rou	
Skin c	orrosion/irritation			
	assified based on availa			
	Is eye damage/eye irri assified based on availa			
	ratory or skin sensitis			
	ensitisation assified based on availa	ble	information.	
•	ratory sensitisation ause allergy or asthma	sym	ptoms or breathin	ng difficulties if inhaled.
<u>Comp</u>	onents:			
Cefuro Result		:	Sensitiser	
	cell mutagenicity			
Not cla	assified based on availa	ble	information.	

<u>Components:</u>

Cefuroxime:



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ersion 3	Revision Date: 30.11.2023	SDS Number: 10844545-00005	Date of last issue: 30.09.2023 Date of first issue: 06.09.2022
Geno	toxicity in vitro	: Test Type: Bac Result: negative	terial reverse mutation assay (AMES)
		Test Type: Chro Result: positive	omosomal aberration
			tro mammalian cell gene mutation test ouse lymphoma cells e
Geno	toxicity in vivo	: Test Type: Micr Species: Mouse Result: negative	9
	nogenicity		
Not cl	lassified based on ava	ailable information.	
-	oductive toxicity		
Not cl	lassified based on ava	ailable information.	
Comp	ponents:		
Cefur	roxime:		
Effect	ts on fertility	: Test Type: Fert Species: Mouse Application Rou Fertility: NOAE Symptoms: No	e ite: Oral _: 6.400 mg/kg body weight
		Test Type: Fert Species: Rabbi Application Rou Fertility: NOAE Symptoms: No	t ite: Oral _: 400 mg/kg body weight
STOT	- single exposure		
Not cl	lassified based on ava	ailable information.	
STOT	- repeated exposur	е	
Not cl	lassified based on ava	ailable information.	
<u>Com</u>	oonents:		
Cefur	roxime:		
Asses	ssment	: May cause dan exposure.	hage to organs through prolonged or repeate
Repe	ated dose toxicity		
Com	oonents:		
	roxime:		
Speci		: Rat	
NOAE		: 900 mg/kg : Subcutaneous	
Applic	cation Route	: Subcutaneous	



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Expo Symp	sure time otoms	: 3 M : No adverse effects
Expo	EL EL cation Route sure time et Organs	 Dog 400 mg/kg 1.600 mg/kg Oral 27 W Blood Gastrointestinal disturbance
Expo	EL cation Route sure time et Organs	 Monkey 450 mg/kg Subcutaneous 1 M Blood, Urinary tract May cause damage to organs.
-	ration toxicity lassified based on ava	ilable information
	rience with human e	
<u>Com</u>	ponents:	
Cefu	roxime:	
	ral Information	: Repeated contact may cause allergic reactions in very sus- ceptible persons.
Inhala	ation	: Symptoms: Nausea, Vomiting, Abdominal pain, vaginitis, Headache, Dizziness, dry mouth, Fatigue, constipation, coliti

SECTION 12: Ecological information

12.1 Toxicity			
Components:			
Cefuroxime:			
Ecotoxicology Assessment Acute aquatic toxicity	:	Toxic effects cannot be excluded	
Chronic aquatic toxicity	:	Toxic effects cannot be excluded	
 12.2 Persistence and degradabilit No data available 12.3 Bioaccumulative potential 	y		
Components:			
Cefuroxime: Partition coefficient: n- octanol/water	:	log Pow: -0,429	



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	i lity in soil ata available			
12.5 Resu	Ilts of PBT and vPvB a	sse	ssment	
<u>Prod</u>	uct:			
Asse	ssment	:	to be either persis	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 Othe	r adverse effects			
Prod	uct:			
Endocrine disrupting poten- : tial		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.		
SECTION	N 13: Disposal consid	dera	ations	
13.1 Wast	te treatment methods			
Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Co				

Contaminated packaging	:	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 han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN 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
ΙΑΤΑ	:	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



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IAT	A	: Not regulated as a dangerous good		
14.3 Tra	nsport hazard class(es			
ADI	N	: Not regulated as a dangerous good		
ADI	र	: Not regulated as a dangerous good		
RID		: Not regulated as a dangerous good		
IMD	G	: Not regulated as a dangerous good		
IAT	A	: Not regulated as a dangerous good		
14.4 Pac	king group			
ADI	N	: Not regulated as a dangerous good		
ADI	र	: Not regulated as a dangerous good		
RID		: Not regulated as a dangerous good		
IMD	G	: Not regulated as a dangerous good		
IAT	A (Cargo)	: Not regulated as a dangerous good		
IAT	A (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 Tra	14.7 Transport in bulk according to Annex II of Marpol and the IBC Code			
Ren	narks	: Not applicable for product as supplied.		
SECTIC	N 15: Regulatory inf	ormation		

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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



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Full	text of H-Statements	;	
H33	4	: May cause allere ties if inhaled.	gy or asthma symptoms or breathing difficul-
H37	3		age to organs through prolonged or repeated
Full	text of other abbrevi	ations	
	p. Sens.)T RE	: Respiratory sense : Specific target o	sitisation rgan toxicity - repeated exposure
Roa ing tion of th Euro asse cy S soci bora Tran ryin tion IMD - Inc KEO tion tion KEO tion tion SVH Stari Goo SVH Tha - Ur	d; AIIC - Australian Inv of Materials; bw - Body (EC) No 1272/2008; C be German Institute for opean Chemicals Ager ociated with x% response accent with x% response accent with x% growth in atory Practice; IARC - hsport Association; IBC g Dangerous Chemical al Civil Aviation Organ G - International Mariti dustrial Safety and Hea CI - Korea Existing Che (Level; NOELR - No emicals; OECD - Organ Chemical Safety and P iament and of the Co tion of Chemicals; RI ods by Rail; SADT - Se IC - Substance of very iland Existing Chemical nited Nations; UNRTDO	ventory of Industrial Che y weight; CLP - Classific CMR - Carcinogen, Muta r Standardisation; DSL - ncy; EC-Number - Europ hse; ELx - Loading rate a sting and New Chemical rate response; GHS - G International Agency for C - International Code for Is in Bulk; IC50 - Half ma ization; IECSC - Invento ime Dangerous Goods; I alth Law (Japan); ISO - emicals Inventory; LC50 - to 50% of a test populat Prevention of Pollution (Adverse) Effect Concern Observable Effect Load hization for Economic Co collution Prevention; PBT es Inventory of Chemicals celationship; REACH - R puncil concerning the R D - Regulations concern elf-Accelerating Decompo y high concern; TCSI - als Inventory; TSCA - To:	nternational Carriage of Dangerous Goods by micals; ASTM - American Society for the Test- cation Labelling Packaging Regulation; Regula- agen or Reproductive Toxicant; DIN - Standard - Domestic Substances List (Canada); ECHA - bean Community number; ECx - Concentration associated with x% response; EmS - Emergen- Substances (Japan); ErCx - Concentration as- Blobally Harmonized System; GLP - Good La- Research on Cancer; IATA - International Air r the Construction and Equipment of Ships car- aximal inhibitory concentration; ICAO - Interna- bry of Existing Chemical Substances in China MO - International Maritime Organization; ISHL International Organisation for Standardization; - Lethal Concentration to 50 % of a test popula- tion (Median Lethal Dose); MARPOL - Interna- from Ships; n.o.s Not Otherwise Specified tration; NO(A)EL - No Observed (Adverse) Ef- ling Rate; NZIoC - New Zealand Inventory of p-operation and Development; OPPTS - Office - Persistent, Bioaccumulative and Toxic sub- s and Chemical Substances; (Q)SAR - (Quanti- egulation (EC) No 1907/2006 of the Europear egistration, Evaluation, Authorisation and Re- ming the International Carriage of Dangerous position Temperature; SDS - Safety Data Sheet Taiwan Chemical Substance Inventory; TECI - xic Substances Control Act (United States); UN ommendations on the Transport of Dangerous pulative

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: Calculation method

Resp. Sens. 1

H334

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



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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.

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