

Cefuroxime Formulation

Version	Revision Date: 2024/09/28	SDS Number:	Date of last issue: 2023/11/30
5.0		10844579-00006	Date of first issue: 2022/09/06

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name	:	Cefuroxime Formulation
Other means of identification	:	Spectrazol Milking Cow (A005270) Coopers Cepravin LC Lactating Cow Intramammary Antibiotic (47941)
Supplier's company name, ad	ldr	ess and phone number
Company name of supplier	:	MSD
Address	:	Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone	:	048-588-8411
E-mail address	:	EHSDATASTEWARD@msd.com
Emergency telephone number	:	+1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chem	product	
Respiratory sensitisation	Category 1	
GHS label elements		
Hazard pictograms		
Signal word	Danger	
Hazard statements	H334 May cause allergy difficulties if inhaled.	v or asthma symptoms or breathing
Precautionary statements	Prevention: P261 Avoid breathing m P284 Wear respiratory p	•
	Response: P304 + P340 IF INHALE	ED: Remove person to fresh air and





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keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 8.33 %

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Cefuroxime	55268-75-2	>= 1 - < 10	-

4. FIRST AID MEASURES

General advice	:	vice immediately.
		When symptoms persist or in all cases of doubt seek medical advice.
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.
		Get medical attention if symptoms occur.
In case of eye contact	:	Flush eyes with water as a precaution.
If swallowed		Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting.
ii Swallowed	•	Get medical attention if symptoms occur.
		Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and	:	
delayed		Excessive exposure may aggravate preexisting asthma and
		other respiratory disorders (e.g. emphysema, bronchitis, reac- tive airways dysfunction syndrome).
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).
Notes to physician	:	Treat symptomatically and supportively.



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5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Nitrogen oxides (NOx) Sulphur oxides
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
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.
Methods and materials for containment and cleaning up	:	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- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-





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		Sections 13 and	ulations are applicable. I 15 of this SDS provide information regarding national requirements.
7. HANDL	ING AND STORAGE		
Hand	ling		
Local	nical measures /Total ventilation e on safe handling	CONTROLS/PE : Use only with a : Do not breathe Do not swallow. Avoid contact w Avoid prolonged Handle in accor practice, based sessment Keep container Already sensitis to asthma, aller	ith eyes. d or repeated contact with skin. dance with good industrial hygiene and safety on the results of the workplace exposure as-
	ance of contact ne measures	 tory irritants or s Take care to pre- environment. Oxidizing agent If exposure to c flushing system place. When using do Wash contamin The effective op engineering cor appropriate deg 	sensitisers. event spills, waste and minimize release to the s hemical is likely during typical use, provide eye s and safety showers close to the working not eat, drink or smoke. ated clothing before re-use. beration of a facility should include review of htrols, proper personal protective equipment, jowning and decontamination procedures, ne monitoring, medical surveillance and the
Stora	ge		
Condi	itions for safe storage	Keep tightly clo Store in accord	ance with the particular national regulations. h the following product types:
Packa	aging material		erial: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components CAS-No. Value type Control parame	e- Basis



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	(Form of	ters / Concentra-	
	exposure)	tion standard / Permissible con- centration	
55268-75-2	TWA	100 µg/m3 (OEB 2)	Internal
Further informa	ation: RSEN		
technologies to less quick con All engineering design and op protect produc	o control airborn nections). g controls should erated in accord ts, workers, and	e concentrations (e.g d be implemented by lance with GMP princ l the environment.	J., drip- facility siples to
If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Particulates type			
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.			re is a
	Use appropria technologies to less quick con All engineering design and op protect produc Laboratory op If adequate loo sure assessme ommended gu Particulates ty Chemical-resis Wear safety gl If the work eny mists or aeros Wear a facesh potential for di aerosols.	Further information: RSEN Use appropriate engineering of technologies to control airborn less quick connections). All engineering controls should design and operated in accord protect products, workers, and Laboratory operations do not r If adequate local exhaust vent sure assessment demonstrate ommended guidelines, use res Particulates type Chemical-resistant gloves Wear safety glasses with side If the work environment or acti mists or aerosols, wear the ap Wear a faceshield or other full potential for direct contact to th aerosols.	centration 55268-75-2 TWA 100 μg/m3 (OEB 2) Further information: RSEN 2)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: liquid
Colour	: white
	off-white
Odour	: No data available
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Boiling point, initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: No data available



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	wer explosion limit and upp Upper explosion limit / Up- per flammability limit			
	Lower explosion limit / Lower flammability limit	:	No data available	9
Fla	sh point	:	No data available	9
De	composition temperature	:	No data available	9
рH		:	No data available	9
Eva	aporation rate	:	No data available	9
Au	to-ignition temperature	:	No data available	9
	cosity Viscosity, kinematic	:	No data available	9
	lubility(ies) Water solubility	:	No data available	9
	rtition coefficient: n- anol/water	:	Not applicable	
Va	pour pressure	:	No data available	9
De	nsity and / or relative densit Relative density	ty :	No data available	9
	Density	:	No data available	9
Re	lative vapour density	:	No data available	9
Ex	plosive properties	:	Not explosive	
Ox	idizing properties	:	The substance o	r mixture is not classified as oxidizing.
Мо	lecular weight	:	No data available	9
Pa	rticle characteristics Particle size	:	Not applicable	

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.



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Incon	itions to avoid npatible materials rdous decomposition ucts	:	None known. Oxidizing agent No hazardous o	s decomposition products are known.
11. TOXIC	OLOGICAL INFORMAT	IO	N	
Inforr expos	nation on likely routes of sure	:	Inhalation Skin contact Ingestion Eye contact	
	e toxicity lassified based on availa	ble	information.	
Com	ponents:			
Cefu	roxime:			
Acute	Acute oral toxicity		LD50 (Rat): > 10),000 mg/kg
			LD50 (Mouse): :	> 10,000 mg/kg
	e toxicity (other routes of nistration)	:	LD50 (Rat): > 4, Application Rou	
			LD50 (Mouse): : Application Rour	
			LD50 (Rabbit): > Application Rou	
			LD50 (Dog): > 1 Application Rou	
	corrosion/irritation lassified based on availa	ble	information.	
	us eye damage/eye irri lassified based on availa			
Resp	iratory or skin sensitis	atic	n	
-	sensitisation lassified based on availa	ble	information.	
-	iratory sensitisation	sym	ptoms or breathin	ng difficulties if inhaled.

Components:

Cefuroxime:

Result

: Sensitiser



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Germ cell mutagenicity

Not classified based on available information.

Components:

Cefuroxime:

•••••	
Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosomal aberration Result: positive
	Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Result: negative

Carcinogenicity

...

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

Cefuroxime:	
Effects on fertility	: Test Type: Fertility Species: Mouse Application Route: Oral Fertility: NOAEL: 6,400 mg/kg body weight Symptoms: No adverse effects
	Test Type: Fertility Species: Rabbit Application Route: Oral Fertility: NOAEL: 400 mg/kg body weight Symptoms: No adverse effects

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Cefuroxime:

Assessment

: May cause damage to organs through prolonged or repeated



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II		exposure.	
Repe	ated dose toxicity		
<u>Com</u>	oonents:		
Cefu	roxime:		
	EL cation Route sure time	: Rat : 900 mg/kg : Subcutaneous : 3 M : No adverse effe	octs
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 t : May cause dam	

Experience with human exposure

Components:

Cefuroxime:

General Information	:	Repeated contact may cause allergic reactions in very sus- ceptible persons.
Inhalation	:	Symptoms: Nausea, Vomiting, Abdominal pain, vaginitis, Headache, Dizziness, dry mouth, Fatigue, constipation, colitis



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12. ECOL	OGICAL INFORMATI	ON		
Ecoto	oxicity			
Com	oonents:			
Cefu	oxime:			
Ecoto	oxicology Assessme	nt		
Acute	aquatic toxicity	:	Toxic effects car	nnot be excluded
Chror	nic aquatic toxicity	:	Toxic effects car	nnot be excluded
	stence and degrada	bility		
Bioad	cumulative potentia	l		
Com	oonents:			
Partit	oxime: ion coefficient: n- ol/water	:	log Pow: -0.429	
	l ity in soil ata available			
	rdous to the ozone la pplicable	ayer		
	adverse effects			
13. DISPC	SAL CONSIDERATI	ONS		
-	osal methods		.	
Waste	e from residues	:		cordance with local regulations. of waste into sewer.
Conta	aminated packaging	:	Empty container dling site for rec	s should be taken to an approved waste h ycling or disposal. specified: Dispose of as unused product.

International Regulations

UNRTDG

UN number	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable



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	ibels ivironmentally hazardous	:	Not applicable no	
UI Pr CI Su Pa ain Pa	TA-DGR N/ID No. Toper shipping name ass ubsidiary risk acking group abels acking instruction (cargo rcraft) acking instruction (passen- er aircraft)		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	
UI Pr CI Su Pa La Er	IDG-Code N number oper shipping name ass ubsidiary risk acking group ubels mS Code arine pollutant		Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable	

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable





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ersion .0	Revision Date: 2024/09/28	SDS Number: 10844579-00006	Date of last issue: 2023/11/30 Date of first issue: 2022/09/06
on Ex	l ar concerning Info kisting Chemicals ha		having Mutagenicity - Annex 2: Informatic
Circu	lar concerning Info	rmation on Chemicals naving Mutagenicity	having Mutagenicity - Annex 1: Informati
	pplicable		
	tances Subject to b	e Notified Names	
	tances Subject to b	e Indicated Names	
	pplicable		
Skin		ibstances for PPE Req	uirements (ISHL MO Art. 594-2)
tions		s (Article 577-2 of the (Occupational Health and Safety Regula-
	nance on Preventior	of Hazards Due to Sp	ecified Chemical Substances
Ordir	ance on Preventior	of Lead Poisoning	
Not a	pplicable	-	
	nance on Preventior	of Tetraalkyl Lead Po	isoning
	nance on Preventior	of Organic Solvent Po	bisoning
Subs	cement Order of the tances)	e Industrial Safety and	Health Law - Attached table 1 (Dangerous
	onous and Deleterio	us Substances Contro	l Law
viron			of Specific Chemical Substances in the Er he Management Thereof
High	Pressure Gas Safet	y Act	
-	pplicable	-	
-	osive Control Law		
	el Safety Law		
	egulated as a danger	ous good	
Aviat	ion Law		
Not re	egulated as a danger		



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Marin	ne Pollution and Sea	Disaster Prevention	etc Law			
Bulk	transportation	: Not classified a	: Not classified as noxious liquid substance			
Pack	transportation	: Not classified a	: Not classified as marine pollutant			
Narc	otics and Psychotrop	oics Control Act				
Not a Spec	Narcotic or Psychotropic Raw Material (Export / Import Permission) Not applicable Specific Narcotic or Psychotropic Raw Material (Export / Import permission) Not applicable					
	Waste Disposal and Public Cleansing Law Industrial waste					
The components of this product are reported in the following inventories:						
AICS		: not determined				
DSL		: not determined				
IECS	С	: not determined				
16 OTHE						

16. OTHER INFORMATION

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/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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



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Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

JP / EN