

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier		
	Trade name	:	Cephapirin (with Peanut Oil) Formulation
	Other means of identification	:	CEFA-SAFE (A007158)
1.2	Relevant identified uses of th	ne s	substance 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	saf	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	ər	
	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	I (EC) No	o 1272/2008)
Hazard pictograms	:	

Signal word

Hazard statements

May cause allergy or asthma symptoms or breath-

Danger

H334

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		ing c	ifficulties if inhaled.
Preca	utionary statements	keep P342 + P311 If	F INHALED: Remove person to fresh air and comfortable for breathing. experiencing respiratory symptoms: Call a SON CENTER/ doctor.

Hazardous components which must be listed on the label:

Cefapirin

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 3.2~%

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)
	Registration number		
Cefapirin	21593-23-7 244-466-5	Resp. Sens. 1A; H334	>= 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 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 s and use the recommended personal protective when the potential for exposure exists (see set of the potential for ex	024 019
If not breathing, give artificial respiration. If not breathing is difficult, give oxygen. Get medical attention. In case of skin contact : Wash with water and soap as a precaution. Get medical attention if symptoms occur. In case of eye contact : Flush eyes with water as a precaution. Get medical attention if symptoms occur. In swallowed : If swallowed : Was cause allergy or asthma symptoms or br ties if inhaled. : : : :	e equipment
Get medical attention if symptoms occur. In case of eye contact : Flush eyes with water as a precaution. Get medical attention if irritation develops and If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water. 4.2 Most important symptoms and effects, both acute and delayed Risks : May cause allergy or asthma symptoms or br ties if inhaled. Excessive exposure may aggravate preexisting other respiratory disorders (e.g. emphysema, tive airways dysfunction syndrome). 4.3 Indication of any immediate medical attention and special treatment needed	
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other respiratory disorders (e.g. emphysema, tive airways dysfunction syndrome).	eathing difficul-
	ł
SECTION 5: Firefighting measures	
5.1 Extinguishing media	
Suitable extinguishing media : Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical	
Unsuitable extinguishing : None known. media	
5.2 Special hazards arising from the substance or mixture	
Specific hazards during fire- : Exposure to combustion products may be a h fighting	azard to health
Hazardous combustion prod- : Carbon oxides ucts Metal oxides	



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5.3 Advice	for firefighters			
	I protective equipment fighters	:		e, wear self-contained breathing apparatus. ective equipment.
Specific extinguishing meth- ods		:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil

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 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- mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures

See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.



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Local/Total ventilation Advice on safe handling Hygiene measures		::	Use only with adequate ventilation. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and s practice, based on the results of the workplace exposure sessment Keep container tightly closed. Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory dise should consult their physician regarding working with res tory irritants or sensitisers. Take care to prevent spills, waste and minimize release environment. If exposure to chemical is likely during typical use, provid flushing systems and safety showers close to the workin place. When using do not eat, drink or smoke. Wash cor	
			nated clothing be The effective ope engineering contr appropriate dego	fore re-use. ration of a facility should include review of rols, proper personal protective equipment, wning and decontamination procedures, a monitoring, medical surveillance and the
7.2 Co	nditions for safe storage,	inc	luding any incom	patibilities
	equirements for storage eas and containers	:		labelled containers. Keep tightly closed. nce with the particular national regulations.
Ac	dvice on common storage	:	Do not store with Strong oxidizing a Gases	the following product types: agents
7.3 Sp	ecific end use(s)			
-	pecific 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
Cefapirin	21593-23-7	TWA	0.4 mg/m3 (OEB 2)	Internal
	Further inform	nation: RSEN		
Aluminum tri- stearate	637-12-7	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL



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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. Equipment should conform to I.S. EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	suspension
Colour	:	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		No data available



Commission Regulation (EU) 2020/878

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	Flash p	point	:	No data available	9
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	рН		:	No data available	9
	Viscosi Visc	ity cosity, kinematic	:	No data available	9
	Solubil Wat	ity(ies) ter solubility	:	No data available	9
	Partitio octano	n coefficient: n- I/water	:	Not applicable	
	Vapou	r pressure	:	No data available	9
	Relativ	e density	:	No data available	9
	Density	4	:	No data available	9
	Relativ	e vapour density	:	No data available	9
		e characteristics ticle size	:	Not applicable	
9.2	Other ir	nformation			
	Explos	ives	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapor	ration rate	:	No data available	9
	Molecu	ılar weight	:	No data available	9

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



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Cond	litions to avoid	:	None known.	
	mpatible materials rials to avoid	:	Oxidizing agent	S
	ardous decomposition azardous decomposition	•		
SECTION	N 11: Toxicological	infor	mation	
	nation on likely routes		as defined in Re Inhalation Skin contact Ingestion Eye contact	gulation (EC) No 1272/2008
	e toxicity lassified based on ava	ilable		
Com	ponents:			
Cefa Acute	pirin: e oral toxicity	:	LD50 (Mouse): 2	26,000 mg/kg
Acute toxicity (other routes of administration)			LD50 (Mouse): > Application Rout	 7,600 mg/kg e: Intraperitoneal
			LD50 (Rat): 7,80 Application Rout	00 mg/kg e: Intraperitoneal
	corrosion/irritation lassified based on ava	ilable	information.	
	ous eye damage/eye i lassified based on ava			
Resp	iratory or skin sensit	isatio	n	
-	sensitisation lassified based on ava	ilable	information.	
-	iratory sensitisation cause allergy or asthm	a sym	ptoms or breathir	ng difficulties if inhaled.
Com	ponents:			
Cefa Asse	pirin: ssment	:	Probability or ev humans	idence of high respiratory sensitisation rate in

SAFETY DATA SHEET

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



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	cell mutagenicity assified based on availa	able i	nformation.		
<u>Comp</u>	onents:				
Cefap Genot	irin: oxicity in vitro	:	Test Type: Bacter Result: negative	ial reverse mutation assay (AMES)	
	n ogenicity assified based on availa	able i	nformation.		
•	ductive toxicity assified based on availa	able i	nformation.		
<u>Comp</u>	onents:				
Cefap Effects	irin: s on fertility	:	Species: Rat Application Route	y/early embryonic development : Intraperitoneal injection > 500 mg/kg body weight on fertility	
Effects ment	s on foetal develop-	:	Species: Rat Application Route	o-foetal development : Intraperitoneal injection oxicity: LOAEL: > 200 mg/kg body weight	
STOT - single exposure Not classified based on available information. STOT - repeated exposure Not classified based on available information. Repeated dose toxicity					

Components:

Cefapirin: Species LOAEL Application Route Target Organs Remarks	:	Rat >= 200 mg/kg Intraperitoneal Blood anemia
Species LOAEL Application Route Exposure time Target Organs	:	Dog 20 mg/kg Oral 4 Months Gastrointestinal tract
Species	:	Dog

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



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 -	Exposu	tion Route ire time Organs		100 mg/kg Intramuscular 10 Months Blood, Gastrointe anemia	stinal tract
	•	tion toxicity	hla	information	
Not classified based on available infor 11.2 Information on other hazards				mormation.	
Endocrine disrupting properties					
<u> </u>	Produc	<u>>t:</u>			
	Assess	ment	:	: 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.	
I	Experie	ence with human exp	osi	ıre	
<u>(</u>	Compo	onents:			
	Cefapi				
	I.a. a. a. a. 4! .			Ourseland a second Maria	a Manditian Abdancia India Diambaga

Ingestion

: Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea, vaginitis, colitis, anorexia, Rash, anaphylaxis

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.



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12.6 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 (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other 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	:	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
ΙΑΤΑ	:	Not regulated as a dangerous good
14.3 Transport hazard class(es)		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good



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RID		Not regula	ted as a dangerous good		
IMDG		Not regulated as a dangerous good			
ΙΑΤΑ		Not regula	ted as a dangerous good		
14.4 Packi	ng group				
ADN		Not regula	ted as a dangerous good		
ADR		Not regula	ted as a dangerous good		
RID		Not regula	ted as a dangerous good		
IMDG		Not regula	ted as a dangerous good		
IATA ((Cargo)	Not regula	ted as a dangerous good		
IATA ((Passenger)	Not regula	ted as a dangerous good		
14.5 Enviro	onmental hazards				
Not regulated as a dangerous good					
-	al precautions for use				
14.7 Mariti	me transport in bulk	ording to IN	IO instruments		
Remai	rks	Not applic	able for product as supplied.		

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Conditions of restriction for the fol- lowing entries should be considered: Number on list 3
		Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.
REACH - Candidate List of Substances of Very High		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 condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not. Not applicable
Concern for Authorisation (Article 59).	•	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable



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•	lation (EU) 2019/1021 c (recast)	on persistent organic p	ollu- :	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- : Not applicable ment and the Council concerning the export and import of dangerous chemicals			Not applicable	
REACH - List of substances subject to authorisation (Annex XIV)			n:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the contro major-accident hazards involving dangerous substances. Not applicable			t and of the Council on the control of	

Other regulations:

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

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	
H334 :	May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.
Full text of other abbreviation	S
Resp. Sens. : IE OEL :	Respiratory sensitisation Ireland. List of Chemical Agents and Carcinogens with Occu- pational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA) :	Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration as-



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sociated 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to :	:	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/

H334

Classification of the mixture:

Resp. Sens. 1

Classification procedure: 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.

IE / EN