Commission Regulation (EU) 2020/878



Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.05.2024
6.0	06.07.2024	493792-00024	Date of first issue: 28.01.2016

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

1.1 Product identifier		
Trade name	:	Cephapirin Formulation
Other means of identification	:	Metricure (A007394) METRICURE BENZATHINE CEPHAPIRIN INTRA-UTERINE SUSPENSION (47091)
1.2 Relevant identified uses of th	ie s	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	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		

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



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Hazaı	rd statements	: H334	May cause allergy or asthma symptoms or breath- ing difficulties if inhaled.
Precautionary statements		: Respon P304 + P342 +	P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Hazardous components which must be listed on the label:

Cefapirin

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

oomponento			
Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Cefapirin	21593-23-7	Resp. Sens. 1A;	>= 1 - < 10
	244-466-5	H334	

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



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			when the potentia	I 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 cas	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 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 ir	nportant symptoms a	nd	effects, both acute	and delayed		
Risks	Risks		May cause allergy ties if inhaled.	or asthma symptoms or breathing difficul-		
			other respiratory of	ire may aggravate preexisting asthma and disorders (e.g. emphysema, bronchitis, reac- nction syndrome).		
4.3 Indication of any immediate m			dical attention and	I special treatment needed		
Treatr	nent	:	Treat symptomati	cally and supportively.		

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
5.2 Special hazards arising from t	the	e substance or mixture
Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides ucts

5.3 Advice for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.



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for firefighters		Use personal pro	otective equipment.
Specific extinguishing meth- ods		cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. aged 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 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

Fo m be Cl be Lo po er m Se	bak up with inert absorbent material. or large spills, provide dyking or other appropriate contain- ent to keep material from spreading. If dyked material can a pumped, store recovered material in appropriate container. lean up remaining materials from spill with suitable absor- ent. bocal or national regulations may apply to releases and dis- bosal of this material, as well as those materials and items nployed in the cleanup of releases. You will need to deter- ine which regulations are applicable. ections 13 and 15 of this SDS provide information regarding ertain local or national requirements.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures	: See Engineering measures under EXPOSURE
	CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: Use only with adequate ventilation.
Advice on safe handling	: Avoid breathing mist or vapours.

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



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Hygiene measures		 Handle in acceleration practice, base sessment Keep contained Already sensities to asthma, alleration should consultation tory irritants on Take care to penvironment. If exposure to flushing system place. When unated clothing The effective of engineering conspropriate defined industrial hygi 	with eyes. ed or repeated contact with skin. ordance with good industrial hygiene and safety d on the results of the workplace exposure as- er tightly closed. ised individuals, and those susceptible ergies, chronic or recurrent respiratory disease, t their physician regarding working with respira-	
7.2 0	Conditi	ons for safe storage,	including any inc	ompatibilities
Requirements for storage areas and containers			rly labelled containers. Keep tightly closed. dance with the particular national regulations.	
Advice on common storage		: Do not store v Strong oxidizin Gases	vith the following product types: ng agents	
700	· · · · ·			

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis	
Cefapirin	21593-23-7	TWA	0.4 mg/m3 (OEB 2)	Internal	
	Further information: RSEN				

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

Substance name	End Use	Exposure routes	Potential health ef- fects	Value
Glycerides, mixed decanoyl and oc- tanoyl	Workers	Inhalation	Long-term systemic effects	177.79 mg/m3



12.61 mg/kg

bw/day

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

Consumers

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		Workers	Skin conta	act	Long-term systemic effects	25.21 mg/kg bw/day
		Consumers	Inhalation		Long-term systemic effects	43.84 mg/m3
		Consumers	Skin conta	act	Long-term systemic effects	12.61 mg/kg bw/day

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

Ingestion

Substance name	Environmental Compartment	Value
Glycerides, mixed decanoyl and	Oral (Secondary Poisoning)	0.03 mg/kg food
octanoyl		

Long-term systemic

effects

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

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



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	Initial b range	oiling point and boiling	:	No data available	•
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available)
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available)
	Flash p	oint	:	No data available)
	Auto-ig	nition temperature	:	No data available)
	Decom	position temperature	:	No data available)
	рН		:	No data available)
	Viscosi Visc	ty cosity, kinematic	:	No data available)
	Solubili Wat	ty(ies) er solubility	:	No data available	
	Partitio octanol	n coefficient: n- /water	:	No data available	
	Vapour	pressure	:	No data available	
	Relative	e density	:	No data available)
	Relative	e vapour density	:	No data available)
		e characteristics icle size	:	No data available)
9.2	Other ir Explosi	nformation		Not explosive	
		ng properties			r mixture is not classified as oxidizing.
		ation rate	•	No data available	, i i i i i i i i i i i i i i i i i i i
	-	lar weight		No data available	
	molecu		•		



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SECTION	N 10: Stability and r	reactivity	
10.1 Reac	tivity		
	lassified as a reactivity	y hazard.	
10.2 Cher	nical stability		
Stable	e under normal condit	ions.	
10.3 Poss	ibility of hazardous	reactions	
Haza	rdous reactions	: Can react with	strong oxidizing agents.
10.4 Cond	litions to avoid		
Cond	itions to avoid	: None known.	
10.5 Incor	mpatible materials		
Mater	rials to avoid	: Oxidizing ager	nts
10.6 Haza	rdous decompositio	n products	
No ha	azardous decompositio	on products are known	
SECTION	N 11: Toxicological	information	

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure	:	Inhalation Skin contact
		Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Cefapirin: Acute oral toxicity	:	LD50 (Mouse): 26,000 mg/kg
Acute toxicity (other routes of administration)	:	LD50 (Mouse): > 7,600 mg/kg Application Route: Intraperitoneal
		LD50 (Rat): 7,800 mg/kg Application Route: Intraperitoneal

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

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ersion)	Revision Date: 06.07.2024		S Number: 3792-00024	Date of last issue: 16.05.2024 Date of first issue: 28.01.2016
Resp	iratory or skin sensiti	isatio	n	
-	sensitisation assified based on avai	ilable i	nformation.	
-	iratory sensitisation cause allergy or asthmatic	a sym	ptoms or breathi	ng difficulties if inhaled.
-	ponents:	,		°
Cefap Asses	birin: ssment	:	Probability or ev humans	vidence of high respiratory sensitisation rate in
	assified based on avai	ilable i	nformation.	
<u>Com</u>	oonents:			
Cefap Geno	birin: toxicity in vitro	:	Test Type: Bact Result: negative	erial reverse mutation assay (AMES)
	nogenicity assified based on avai	ilable i	nformation.	
-	oductive toxicity assified based on avai	ilable i	nformation.	
<u>Comp</u>	oonents:			
Cefar Effect	birin: is on fertility	:	Species: Rat Application Rou	ility/early embryonic development ite: Intraperitoneal injection .: > 500 mg/kg body weight cts on fertility
Effect ment	s on foetal develop-	:	Species: Rat Application Rou	oryo-foetal development ite: Intraperitoneal injection Toxicity: LOAEL: > 200 mg/kg body weight
	- single exposure assified based on avai	ilable i	nformation.	
	- repeated exposure assified based on avai		nformation.	
	ated dose toxicity			
Comr	oonents:			

Components:

Cefapirin:

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	EL cation Route et Organs	: Rat : >= 200 mg/kg : Intraperitoneal : Blood : anemia		
Expo		: Dog : 20 mg/kg : Oral : 4 Months : Gastrointestina	al tract	
Expo	EL cation Route sure time et Organs	: Dog : 100 mg/kg : Intramuscular : 10 Months : Blood, Gastroi : anemia	ntestinal tract	

Aspiration toxicity

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

Experience with human exposure

Components:

Cefapirin:

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



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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.

12.6 Endocrine disrupting properties

Product:	
Assessment	: 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.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

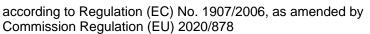
13.1 Waste treatment methods

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.
Contaminated packaging	 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 or ID number	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





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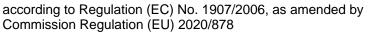
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ADR		-	a dangerous good		
RID		Not regulated as	s a dangerous good		
IMDG		: Not regulated as a dangerous good			
ΙΑΤΑ		Not regulated as	s a dangerous good		
14.3 Trans	port hazard class(es)				
ADN		Not regulated as	a dangerous good		
ADR		Not regulated as	a dangerous good		
RID		Not regulated as	a dangerous good		
IMDG		Not regulated as	s a dangerous good		
ΙΑΤΑ		Not regulated as	s a dangerous good		
14.4 Packi	ng group				
ADN		Not regulated as	s a dangerous good		
ADR		Not regulated as	a dangerous good		
RID		Not regulated as	s a dangerous good		
IMDG		Not regulated as	a dangerous good		
ΙΑΤΑ	(Cargo)	Not regulated as	a dangerous good		
ΙΑΤΑ	(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 Mariti	me transport in bulk	ording to IMO ins	struments		
Rema	rks	Not applicable for	or 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 following entries should be considered: Number on list 75, 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or





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					not.
					If you intend to use this product as tattoo ink, please contact your ven- dor.
		Substances of Very Hig	ıh	:	Not applicable
Reg		Article 59). 2009 on substances that	de-	:	Not applicable
	e the ozone layer julation (EU) 2019/1021	l on persistent organic p	ollu-	:	Not applicable
tant	s (recast)				
mer	,	12 of the European Parl erning the export and im		:	Not applicable
RE/	0	s subject to authorisation	n	:	Not applicable
•	,	18/EU of the European F	Parliame	en	t and of the Council on the control of

major-accident hazards involving dangerous substances. Not applicable

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 abbreviations	
Resp. Sens. :	Respiratory sensitisation

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 Test-



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ing 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; 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 : compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Classification of the mixture:

Classification procedure: Calculation method

Resp. Sens. 1

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

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 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

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



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