According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.05.2024

 6.0
 06.07.2024
 9372548-00010
 Date of first issue: 27.08.2021

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 the 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 safety data sheet

Company : MSD

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 6.0 06.07.2024 9372548-00010 Date of first issue: 27.08.2021

Hazard pictograms :

Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breath-

ing difficulties if inhaled.

Precautionary statements : Response:

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

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.

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 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).

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 6.0 06.07.2024 9372548-00010 Date of first issue: 27.08.2021

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 : 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 important symptoms and effects, both acute and delayed

Risks May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically 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 the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides

5.3 Advice for firefighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.05.2024

 6.0
 06.07.2024
 9372548-00010
 Date of first issue: 27.08.2021

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.

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.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

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 containment 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 disposal 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.

Local/Total ventilation : Use only with adequate ventilation. Advice on safe handling : Avoid breathing mist or vapours.

Do not swallow.

Avoid contact with eyes.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.05.2024

 6.0
 06.07.2024
 9372548-00010
 Date of first issue: 27.08.2021

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami-

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

use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Gases

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	Control parameters	Basis
		of exposure)		
Cefapirin	21593-23-7	TWA	0.4 mg/m3 (OEB 2)	Internal
	Further information: RSEN			

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health ef-	Value
			fects	
Glycerides, mixed decanoyl and octanoyl	Workers	Inhalation	Long-term systemic effects	177.79 mg/m3
	Workers	Skin contact	Long-term systemic effects	25.21 mg/kg bw/day

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.05.2024

 6.0
 06.07.2024
 9372548-00010
 Date of first issue: 27.08.2021

Consumers	Inhalation	Long-term systemic effects	43.84 mg/m3
Consumers	Skin contact	Long-term systemic effects	12.61 mg/kg bw/day
Consumers	Ingestion	Long-term systemic effects	12.61 mg/kg bw/day

Predicted No Effect Concentration (PNEC):

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

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 : Work uniform or laboratory coat.

Respiratory protection : 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 BS 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

Appearance : suspension
Colour : No data available
Odour : No data available
Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

Flash point

No data available

: No data available

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 6.0 06.07.2024 9372548-00010 Date of first issue: 27.08.2021

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

Relative density : No data available

Solubility(ies)

Water solubility : Partition coefficient: n-

Auto-ignition temperature

octanol/water

No data available No data available

: No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

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.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 6.0 06.07.2024 9372548-00010 Date of first issue: 27.08.2021

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of : Inhalation

exposure 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 : LD50 (Mouse): > 7,600 mg/kg

administration)

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.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

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

Components:

Cefapirin:

Assessment : Probability or evidence of high respiratory sensitisation rate in

humans

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 16.05.2024 6.0 06.07.2024 9372548-00010 Date of first issue: 27.08.2021

Germ cell mutagenicity

Not classified based on available information.

Components:

Cefapirin:

Genotoxicity in vitro Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

Cefapirin:

Effects on fertility Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Intraperitoneal injection Fertility: LOAEL: > 500 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intraperitoneal injection

Developmental Toxicity: 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 Rat

LOAEL >= 200 mg/kg Application Route Intraperitoneal

Target Organs Blood Remarks anemia

Species Dog LOAEL 20 mg/kg Application Route Oral

Exposure time 4 Months

Target Organs Gastrointestinal tract

Species Dog

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.05.2024

 6.0
 06.07.2024
 9372548-00010
 Date of first issue: 27.08.2021

LOAEL : 100 mg/kg
Application Route : Intramuscular
Exposure time : 10 Months

Target Organs : Blood, Gastrointestinal tract

Remarks : anemia

Aspiration toxicity

Not classified based on available information.

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

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 Other adverse effects

Product:

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 6.0 06.07.2024 9372548-00010 Date of first issue: 27.08.2021

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

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
IATA : 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
IATA : 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
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

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
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 16.05.2024 06.07.2024 9372548-00010 Date of first issue: 27.08.2021 6.0

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) Conditions of restriction for the fol-

lowing entries should be considered:

Number on list 3

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

not.

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

UK REACH List of substances subject to authorisation

(Annex XIV)

GB Export and import of hazardous chemicals - Prior

Informed Consent (PIC) Regulation Control of Major Accident Hazards Regulations 2015 (COMAH)

Not applicable

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

The components of this product are reported in the following inventories:

AICS not determined

DSL not determined

IECSC not determined

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.05.2024

 6.0
 06.07.2024
 9372548-00010
 Date of first issue: 27.08.2021

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 Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods: vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to : compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Cephapirin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.05.2024

 6.0
 06.07.2024
 9372548-00010
 Date of first issue: 27.08.2021

Sheet cy, http://echa.europa.eu/

Classification of the mixture: Classification procedure:

Resp. Sens. 1 H334 Calculation method

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

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.

GB / EN