

Cefalexin Formulation

Version Revision Date: SDS Number: Date of last issue: 26.11.2024 2.0 14.04.2025 11474867-00002 Date of first issue: 26.11.2024

Section 1: Identification

Product identifier : Cefalexin Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

Manufacturer or supplier's details

Company : MSD

Address : 50 Tuas West Drive

Singapore - Singapore 638408

Telephone : +1-908-740-4000

Emergency telephone number : 65 6697 2111 (24/7/365)

E-mail address : EHSDATASTEWARD@msd.com

Section 2: Hazard identification

Classification of the substance or mixture

Respiratory sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - :

single exposure

Category 3

Specific target organ toxicity - :

repeated exposure

Category 2 (Kidney, Adrenal gland, Blood, Gastrointestinal

tract)

GHS Label elements, including precautionary statements

Hazard pictograms :





Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

H335 May cause respiratory irritation. H361f Suspected of damaging fertility.

H373 May cause damage to organs (Kidney, Adrenal gland, Blood, Gastrointestinal tract) through prolonged or repeated





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exposure.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapours.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection/ hearing protection. P284 Wear respiratory protection.

Response:

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/

doctor if you feel unwell.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

Storage:

P405 Store locked up.

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: 21 %

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) | |
|---------------|------------|-----------------------|--|
| Cefalexin | 15686-71-2 | >= 20 -< 30 | |

Section 4: First-aid measures

Description of necessary 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.



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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.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

Flush eyes with water as a precaution

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.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

Risks : Excessive exposure may aggravate preexisting asthma and

other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

May cause respiratory irritation. Suspected of damaging fertility.

May cause damage to organs through prolonged or repeated

exposure.

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).

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

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: :

ucts

Nitrogen oxides (NOx)

Sulphur oxides

Carbon oxides





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Special protective actions for fire-fighters

for firefighters

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

Use personal protective equipment.

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

Evacuate area.

Section 6: Accidental release measures

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).

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

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

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.

Section 7: Handling and storage

Precautions for safe handling

Technical measures See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation If sufficient ventilation is unavailable, use with local exhaust

ventilation.



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Advice on safe handling : 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 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 respira-

tory 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 contaminated 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.

Conditions for safe storage, including any incompatibilities

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis | |
|------------|---------------------------|-------------------------------------|--|----------|--|
| Cefalexin | 15686-71-2 | TWA | 550 μg/m3 (OEB 2) | Internal | |
| | Further information: RSEN | | | | |

Appropriate engineering control measures

: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-

less quick connections).





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> 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.

Individual protection measures, such as personal protective equipment (PPE)

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.

Work uniform or laboratory coat. Skin protection

If adequate local exhaust ventilation is not available or expo-Respiratory protection

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Combined particulates and organic vapour type

Filter type Hand protection

Material Chemical-resistant gloves

Section 9: Physical and chemical properties

Appearance liquid

Colour clear

Odour No data available

Odour Threshold No data available

No data available pΗ

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

No data available Flash point

Evaporation rate 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

flammability limit

: No data available



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Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Auto-ignition temperature : 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.

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

Section 11: Toxicological information

Information on likely routes of : Inhalation

exposure S

Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.



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Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

Cefalexin:

Acute oral toxicity : LD50 (Mouse): 1,600 - 6,200 mg/kg

LD50 (Dog): > 2,000 mg/kg

Symptoms: Vomiting

LD50 (Monkey): > 1,000 mg/kg

Symptoms: Vomiting

LD50 (Rat): > 20,000 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Dog): > 1 g/kg

Application Route: Intraperitoneal

LD50 (Dog): > 0.1 g/kg

Application Route: Intravenous

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:

Cefalexin:

Assessment : Probability or evidence of high respiratory sensitisation rate in

humans

Remarks : Based on data from similar materials

May cause sensitisation by inhalation.

Result : Sensitiser

Remarks : Based on data from similar materials

May cause sensitisation by inhalation.

Germ cell mutagenicity

Not classified based on available information.



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Components:

Cefalexin:

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

Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells

Result: negative

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

Suspected of damaging fertility.

Components:

Cefalexin:

Effects on fertility : Test Type: Two-generation study

Species: Rat

Application Route: Oral

Fertility: NOAEL: 250 mg/kg body weight

Result: May cause adverse reproductive effects., Reduced

fertility of F1 generation

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse

Application Route: Oral

Embryo-foetal toxicity: NOAEL: 400 mg/kg body weight Remarks: No significant adverse effects were reported

Maternal toxicity observed.

Test Type: Development

Species: Rat

Application Route: Oral

Embryo-foetal toxicity: NOAEL: 1,200 mg/kg body weight Remarks: No significant adverse effects were reported

Maternal toxicity observed.

Reproductive toxicity - As-

sessment

: Suspected of damaging fertility.

STOT - single exposure

May cause respiratory irritation.



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Components:

Cefalexin:

Exposure routes : Inhalation

Assessment : May cause respiratory irritation.

STOT - repeated exposure

May cause damage to organs (Kidney, Adrenal gland, Blood, Gastrointestinal tract) through prolonged or repeated exposure.

Components:

Cefalexin:

Target Organs : Kidney, Adrenal gland, Blood, Gastrointestinal tract

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Cefalexin:

Species : Rat

NOAEL : < 160 mg/kg

Application Route : Oral

Target Organs : Kidney, Adrenal gland, Blood

Symptoms : Vomiting, Diarrhoea, Kidney disorders, Blood disorders

Species : Dog

NOAEL : < 160 mg/kg

Application Route : Oral

Target Organs : Kidney, Adrenal gland, Blood

Symptoms : Vomiting, Diarrhoea, Blood disorders, Kidney disorders

Species : Monkey NOAEL : < 160 mg/kg

Application Route : Oral

Target Organs : Kidney, Adrenal gland, Blood

Symptoms : Vomiting, Diarrhoea, Blood disorders, Kidney disorders

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Cefalexin:

Inhalation : Target Organs: Respiratory Tract

Remarks: May cause irritation of respiratory tract.

May cause sensitisation by inhalation.

Ingestion : Target Organs: Gastrointestinal tract



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Symptoms: The most common side effects are:, Nausea, Vomiting, Abdominal pain, Diarrhoea, liver function change,

blood effects

Section 12: Ecological information

Toxicity

Components:

Cefalexin:

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Section 13: Disposal considerations

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

no

Dispose of in accordance with local regulations.

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

International Regulations

UNRTDG

UN number : Not applicable
UN proper shipping name : Not applicable
Transport hazard class(es) : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous :

IATA-DGR



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UN/ID No. : UN 3334

UN proper shipping name : Aviation regulated liquid, n.o.s.

964

(Cefalexin)

Transport hazard class(es) : 9
Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen: 964

ger aircraft)

IMDG-Code

UN number Not applicable UN proper shipping name Not applicable Transport hazard class(es) Not applicable Subsidiary risk Not applicable Packing group Not applicable Not applicable Labels **EmS Code** Not applicable Not applicable Marine pollutant

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subject to the requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable

Environmental Protection and Management (Hazard-

ous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable

Regulations

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

DSL : not determined

AICS : not determined

IECSC : not determined

Section 16: Other information

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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 Agen-

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 : dd.mm.yyyy

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 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



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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.

SG / EN