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Cefquinome (7.5%) LA Formulation

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1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cefquinome (7.5%) LA Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number: +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Skin corrosion/irritation : Category 3

Respiratory sensitisation : Category 1

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 2

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H316 Causes mild skin irritation.

H334 May cause allergy or asthma symptoms or breathing

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difficulties if inhaled.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P261 Avoid breathing mist or vapours. P273 Avoid release to the environment. P284 Wear respiratory protection.

Response:

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

keep comfortable for breathing.

P332 + P317 If skin irritation occurs: Get medical help.

P342 + P316 If experiencing respiratory symptoms: Get emer-

gency medical help immediately.

P391 Collect spillage.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cefquinome	118443-89-3	>= 5 - < 10
Dihydroxyaluminium stearate	7047-84-9	>= 1 - < 5

4. 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.

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 plenty of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

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.

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Get medical attention if symptoms occur.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

Causes mild skin irritation.

delayed

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).

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Hazardous combustion prod-

Carbon oxides
Nitrogen oxides (NOx)

ucts

Sulphur oxides
Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

Exposure to combustion products may be a hazard to health.

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for firefighters

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

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.

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Clean up remaining materials from spill with suitable absor-

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 determine which regulations are applicable.

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation. Advice on safe handling : Do not get on skin or clothing.

Avoid breathing mist or vapours.

Do not swallow.

Avoid contact with eyes.

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.

Conditions for safe storage : Keep in properly labelled containers.

Keep tightly closed.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cefquinome	118443-89-3	TWA	2000 μg/m3 (OEB 1)	Internal
	Further information: RSEN			
Dihydroxyaluminium stearate	7047-84-9	TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
		TWA (Res-	1 mg/m3	ACGIH

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pirable particulate matter) (Aluminium)

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

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

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

Eye 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.

Skin and body protection : Work uniform or laboratory coat.

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.

9. 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 : No data available

according to the Globally Harmonized System



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range

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

No data available Vapour pressure

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

Not applicable

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 size Not applicable

10. STABILITY AND REACTIVITY

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

tions

Conditions to avoid None known. Incompatible materials Oxidizing agents

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Hazardous decomposition

products

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure

Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Cefquinome:

Acute oral toxicity : LD50 (Mouse): > 5,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Dihydroxyaluminium stearate:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Method: OECD Test Guideline 423

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Guinea pig): > 3,000 mg/kg

Skin corrosion/irritation

Causes mild skin irritation.

Components:

Cefquinome:

Result : Irritating to skin.

Dihydroxyaluminium stearate:

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 439

Remarks : Based on data from similar materials

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

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Components:

Cefquinome:

Result : Irritating to eyes.

Dihydroxyaluminium stearate:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Remarks : Based on data from similar materials

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:

Cefquinome:

Exposure routes : Inhalation

Result : May cause sensitisation by inhalation.

Dihydroxyaluminium stearate:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact
Species : Mouse
Result : negative

Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Dihydroxyaluminium stearate:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

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Reproductive toxicity

Not classified based on available information.

Components:

Dihydroxyaluminium stearate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

Components:

Cefquinome:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Dihydroxyaluminium stearate:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Cefquinome:

Inhalation : Symptoms: anaphylaxis, bronchospasm, Cough, respiratory

tract irritation, Rash, rhinitis, runny nose, sneezing

Remarks: May produce an allergic reaction.

Skin contact : Remarks: May irritate skin.

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May produce an allergic reaction.

Eye contact : Remarks: May irritate eyes.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cefquinome:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 500 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 86

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 37

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 0.041 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.014 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

10

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 295.3 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

M-Factor (Chronic aquatic

toxicity)

1

Dihydroxyaluminium stearate:

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Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Ecotoxicology Assessment

Chronic aquatic toxicity : No toxicity at the limit of solubility

Persistence and degradability

Components:

Cefquinome:

Biodegradability : Result: not rapidly degradable

Biodegradation: 40 % Exposure time: 30 d

Method: OECD Test Guideline 302B

Stability in water : Hydrolysis: > 90 %(5 d)

Method: FDA 3.09

Dihydroxyaluminium stearate:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Cefquinome:

Partition coefficient: n-

log Pow: -2.01

octanol/water

Dihydroxyaluminium stearate:

Partition coefficient: n- : log Pow: 7.48

octanol/water Remarks: Calculation

Mobility in soil

Components:

Cefquinome:

Distribution among environ-

mental compartments

log Koc: 2.76

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Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

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

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Cefquinome)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Cefquinome)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen-

964

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Cefquinome)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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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.

15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 30.09.2023

Further information

Sheet

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-

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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

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Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IN / EN