

Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 18.12.2015

Version number 4

Revision: 18.12.2015

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

1.1 Product identifier

Trade name: RIDA® Ciprofloxacin Spiking Solution

Article number: R3198S00

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Application of the substance / the preparation: In vitro

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

R-Biopharm AG

An der neuen Bergstraße 17

D-64297 Darmstadt

Further information obtainable from: FE e-mail: info@r-biopharm.de

1.4 Emergency telephone number: FE 0049-6151-8102-0

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



GHS02 flame

Flam. Liq. 3 H226 Flammable liquid and vapour.



GHS06 skull and crossbones

Acute Tox. 3 H331 Toxic if inhaled.



GHS08 health hazard

STOT SE 1 H370 Causes damage to organs.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC



T+; Very toxic

R39/27/28: Very toxic: danger of very serious irreversible effects in contact with skin and if swallowed.



T; Toxic

R23: Toxic by inhalation.

R10: Flammable.

Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Hazard pictograms GHS02, GHS06, GHS08

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Signal word Danger**Hazard-determining components of labelling:**

methanol

Hazard statements

H226 Flammable liquid and vapour.

H331 Toxic if inhaled.

H370 Causes damage to organs.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P241 Use explosion-proof electrical/ventilating/lighting/equipment.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards**Results of PBT and vPvB assessment****PBT:** Not applicable.**vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures**Description:** Mixture: consisting of the following components.**Dangerous components:**

CAS: 67-56-1	methanol	25-50%
EINECS: 200-659-6	T R23/24/25-39/23/24/25 F R11	
	Flam. Liq. 2, H225	
	Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331	
	STOT SE 1, H370	

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures**General information:**

Immediately remove any clothing soiled by the product.

Remove breathing equipment only after contaminated clothing have been completely removed.

In case of irregular breathing or respiratory arrest provide artificial respiration.

After inhalation:

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

After skin contact: Immediately wash with water and soap and rinse thoroughly.**After eye contact:**

Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing: If symptoms persist consult doctor.**4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

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4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing agents:**CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.**For safety reasons unsuitable extinguishing agents:** Water with full jet**5.2 Special hazards arising from the substance or mixture**

During heating or in case of fire poisonous gases are produced.

5.3 Advice for firefighters**Protective equipment:** Mouth respiratory protective device.**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Mount respiratory protective device.

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions:

Prevent seepage into sewage system, workpits and cellars.

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Keep respiratory protective device available.

7.2 Conditions for safe storage, including any incompatibilities**Storage:****Requirements to be met by storerooms and receptacles:** No special requirements.**Information about storage in one common storage facility:** Not required.**Further information about storage conditions:** Keep container tightly sealed.**7.3 Specific end use(s)** No further relevant information available.**SECTION 8: Exposure controls/personal protection****Additional information about design of technical facilities:** No further data; see item 7.

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8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

67-56-1 methanol

WEL	Short-term value: 333 mg/m ³ , 250 ppm Long-term value: 266 mg/m ³ , 200 ppm Sk
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Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

Personal protective equipment:
General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Respiratory protection: Not required.

Protection of hands:


Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

For the permanent contact gloves made of the following materials are suitable:

Nitrile rubber, NBR

 Recommended thickness of the material: ≥ 0.11 mm

 Value for the permeation: Level ≤ 480
As protection from splashes gloves made of the following materials are suitable:

Nitrile rubber, NBR

 Recommended thickness of the material: ≥ 0.11 mm

 Value for the permeation: Level ≤ 480
Eye protection:


Tightly sealed goggles

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information
Appearance:
Form: Fluid

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Colour:	Colourless
Odour:	Characteristic
Odour threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	80 °C
Flash point:	31 °C
Flammability (solid, gaseous):	Not applicable.
Ignition temperature:	455 °C
Decomposition temperature:	Not determined.
Self-igniting:	Product is not selfigniting.
Danger of explosion:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
Explosion limits:	
Lower:	5.5 Vol %
Upper:	44.0 Vol %
Vapour pressure at 20 °C:	128 hPa
Density at 20 °C:	0.94038 g/cm ³
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with water:	Not miscible or difficult to mix.
Partition coefficient (n-octanol/water):	Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
Solvent content:	
Organic solvents:	35.0 %
Water:	63.8 %
Solids content:	1.2 %
9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: No dangerous decomposition products known.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Toxic if inhaled.

LD/LC50 values relevant for classification:

67-56-1 methanol

Oral	LD50	5628 mg/kg (rat)
Dermal	LD50	15800 mg/kg (rabbit)

Primary irritant effect:

Skin corrosion/irritation Based on available data, the classification criteria are not met.**Serious eye damage/irritation** Based on available data, the classification criteria are not met.**Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Germ cell mutagenicity Based on available data, the classification criteria are not met.**Carcinogenicity** Based on available data, the classification criteria are not met.**Reproductive toxicity** Based on available data, the classification criteria are not met.

STOT-single exposure

Causes damage to organs.

STOT-repeated exposure Based on available data, the classification criteria are not met.**Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.**12.2 Persistence and degradability** No further relevant information available.**12.3 Bioaccumulative potential** No further relevant information available.**12.4 Mobility in soil** No further relevant information available.

Additional ecological information:

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.**vPvB:** Not applicable.**12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Disposal must be made according to official regulations.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

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SECTION 14: Transport information

14.1 UN-Number
ADR, IMDG, IATA

UN1992

14.2 UN proper shipping name
ADR

1992 FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL)

IMDG
IATA

 FLAMMABLE LIQUID, TOXIC, N.O.S. mixture
 Flammable liquids, toxic, n.o.s. (Methanol)
14.3 Transport hazard class(es)**ADR**
Class
Label

 3 (FT1) Flammable liquids.
 3+6.1
IMDG
Class
Label

 3 Flammable liquids.
 3/6.1
IATA
Class
Label

 3 Flammable liquids.
 3 (6.1)

14.4 Packing group
ADR, IMDG, IATA

II

14.5 Environmental hazards:
Marine pollutant:

No

14.6 Special precautions for user

Warning: Flammable liquids.

Danger code (Kemler):

336

EMS Number:

F-E,S-D

Stowage Category

B

Stowage Code

SW2 Clear of living quarters.

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

Not applicable.

Transport/Additional information:**ADR****Limited quantities (LQ)**

1L

Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

Transport category

2

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Tunnel restriction code	D/E
IMDG	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 1992 FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL), 3 (6.1), II

SECTION 15: Regulatory information

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

Directive 2012/18/EU

Named dangerous substances - ANNEX I methanol

Seveso category

H2 ACUTE TOXIC

P5c FLAMMABLE LIQUIDS

Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t

Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t

National regulations:

Waterhazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

H370 Causes damage to organs.

R11 Highly flammable.

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R39/23/24/25 Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.

Department issuing MSDS: QS 0049-6151-8102-0

Contact: QS 0049-6151-8102-0

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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Flam. Liq. 2: Flammable liquids, Hazard Category 2
Flam. Liq. 3: Flammable liquids, Hazard Category 3
Acute Tox. 3: Acute toxicity, Hazard Category 3
STOT SE 1: Specific target organ toxicity - Single exposure, Hazard Category 1

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*** Data compared to the previous version altered.**

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