



according to regulation (EC) 1907/2006 (REACH)

Product and Company Identification

1.1 Product identification

Product name: BE LTA Ris 15

Product identifier: Ristocetin-Reagenz 15 mg/ ml

Ref. No.: 057651 CAS No.: Not applicable

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

for in vitro use only following Chapter 7.3 and 16.1. Any other use is disadvised.

1.3 Details of the supplier of this safety data sheet

Company Kommanditgesellschaft Behnk Elektronik GmbH & Co.

Hans-Böckler-Ring 27 22851 Norderstedt

Germany

Phone + 49 (40) 529861 10 Fax + 49 (40) 529861 99 E-Mail info@behnk.de

1.4 Emergency call

+ 49 5261 927294 (Mo - Fr 8 am - 5 pm)

Call local authorities alternatively

2 Hazards Identification

2.1 Classification of substance or mixture

This product does not meet the criteria for classification in accordance with regulation No. 1272/2008 EC

2.2 Label elements

None

Signal word: not required

Hazard statements:

Not required

Precautionary statements:

Not required

2.3 Other Hazards

There is no additional hazard information available. This product does not contain any substances or components in amount of 0.1 % or higher that are classified as persistent, bioaccumulating or toxic PBT).

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3 Composition / Information on ingredients

3.1 Substances

Name:Ristocetin, SulfatsalzChemical Formula: $C_{95}H_{110}N_8O_{44} \times H_2SO_4$

Molecular Weight: 2166.00 CAS-No.: 11140-99-1 EG-No.: not applicable Name: **D-Mannit** Chemische Formel: $C_6H_{14}O_6$ Molekulargewicht: 182.18 CAS-No.: 69-65-8 EG-No.: 2007118

Name: Sodium chloride

Chemical Formula: NaCl
Molecular Weight: 58.44
CAS-No.: 7647-14-5
EG-No.: 2315983





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4 First Aid Measures

4.1 Description of First Aid measures

General information

If any symptoms occur or when in doubt, consult medical attention and show this safety data sheet, if possible. Do not leave victims unattended.

After inhalation:

Provide fresh air. In case of breathing arrest apply artificial respiration.

After skin contact:

Remove contaminated clothes immediately. Rinse with plenty of detergent and water. In case of skin irritation seek medical advise.

After eye contact:

Rinse immediately with plenty of water for at least 15 min while holding eyelids opened. Remove contact lenses if possible. Continuous rinsing. Seek medically attention in any cases, preferably to an ophthalmologist

After ingestion:

Rinse mouth with water. Do not induce womiting. Immediately seek medical attention. Do not give anything by mouth to an unconcious person.

4.2 Most important symptoms and effects, both acute and delayed

Most important symptoms and effects, if known, are descriped on the hazardous information label (see chapter 2.2), or are described in chaper 11, respectively.

4.3 Indication of any immediate medical attention and special treatment needed

Increased platelet aggregation may occur after contact with wounds or intrusion in the blood circuit.

5 Fire Fighting Measures

5.1 Extinguishing fire fighting media

Suitable extinguishing media

Product itself is not combustible. Adapt fire fighting measures to the fire surrounding areas. Use water spray, carbon dioxide, foam, dry extinguishing powder Unsuitable extinguishing media Water jet.

5.2 Special hazard arising from the substance or mixture

In case of fire, due to the fire or high temperature, hazardous fumes or gases may be liberated.

Hazardous combustion products:

Carbon monoxide, sulphur oxides.

5.3 Advice for fire fighters

Fight fire with normal precaucions from a reasonable distance. If advised, wear self-contained breathing apparatu.

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5.4 Additional information

There is no further information available.





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6 Accidential Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Refer to the informations and measures given in chapters 7 and 8. Avoid dust formation. Do not breathe gas/mist/vapours.

6.2 Environmental precautions

No further precautions or measures needed. Avoid release to the environment. Keep product away from drains or other water courses.

6.3 Methods and material for containment and cleaning-up

Do not return spilled material back in original package. Wipe up spilled material with non-woven or other suitable absorbent material. Clean contaminated surfaces with pure water. Dispose the product and any components in suitable, closed and labelled containers. Absorb spillage to prevent material damage. All measures of containment and disposal must be in accordance to local requirements and regulations.

6.4 Cross reference to other related sections

Refer to section 13 for disposal. Refer to section 8 for personal protection.

7 Handling and Storage

7.1 Precautions for safe handling

Do not leave containers opened after use. Do not eat, drink or smoke during working time. Keep away from food, drink and animal feeding stuff. Wash hands before breaks and after work. Avoid contact to skin, mucosa, eyes or lesions. Do not inhale vapors/mists/aerosols. Use ventilation if necessary. Refer to section 2.2 for further safety information.

7.2 Conditions for safe storage, including any incompatibilities

Store chilled at a dry and dark place. Keep all containers tightly closed. Refer to the kit imprint or label for the recommended storage temperature. Keep all components always in their original package. Keep opened containers tightly closed in upright position in order to prevent leakage. Uncompatible materials Strong oxidation agents, strong acids and bases. If used in accordance to specific use mentioned in sections 1.2, 7.3, 16.1, no incompatibilities or hazardous reactions may be expected.

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7.3 Specific end use

For in vitro diagnostical use only following the instructions for use of the product.





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8 Exposure Controls / Personal Protection

8.1 Control Parameters

Occupational exposure limits values (Workplace exposure limits)

No data available.

Biological limit values

No data available.

8.2 Exposure controls

Appropriate engineering controls

Take usual measures for good health and safety, and hygiene practice.

Personal protective equipment

Eye protection

Use safety goggle with side protection. All equipment used must be tested and approved under appropriate government standard such as US-NIOSH or EU-EN 166.

Hand/skin protection

Use gloves made of natural rubber or nitrile rubber in accordance to EU directive 89/686/EWG and EN374 norm. Usage of cotton-made gloves under rubber-made gloves is recommended in order to avoid skin irritance.

Body protection

Wash and dry hands after work and before breaks. Use protective clothes in accordance to the local applicable rules and the specific work place.

Respiratory protection

Respiratory protection is usually not necessary. In case of aerosol or mist formation use dust mask with P2 filter.

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Working space with ventilation or a dust extractor is preferred.

Environmental exposure control

Keep away from drains, surface or ground water. Avoid release to the environment.

9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance colorless or light yellow freeze dried pellet

Physical state solid

Colour colourless or light yellow

Odour odourless
Odour threshold not applicable

pH value 7 ... 8

Melting point / range not applicable Softening point not applicable Initial boiling point / range not determined Flash point not combustible **Evaporation** rate not determined Vapour pressure not determined Vapour density not determined Flammability not combustible Ignition point not relevant Lower explosion limit not relevant Upper explosion limit not relevant Relative denisty no data available **Bulk density** not determined

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Water solubility soluble

Solubility in other solvents no data available

Partitition coefficient:

n-Octanol / Water no data available

Auto-ignition temperature not combustible
Decompostion point not determined
Viscosity not applicable
Explosive properties not explosive
Oxidizing properties not oxidizing

9.2 Other information

There are no additional data or information available.

10 Stability and Reactivity

10.1 Reactivity

Stable at storage and usage conditions. By normal use according to the aims mentioned in sections 1.2, 7.3, 16.1, incidental reactions are not to be expected.

10.2 Chemical stability

The product is stable if it is stored and handled under the conditions recommended in sections 1.2, 7.3, 16.1

10.3 Possibility of hazardous reactions

If the product is stored, used and handled for the intended purpose, no hazardous reactions are to be expected.

10.4 Conditions to avoid

Strong basic, acid or oxidizing conditions and heating should be avoided. Not to be expected for intended use.

10.5 Incompatible materials

Strong basic, acid or oxidizing agents, differnet metals. Not to be expected for intended use.

10.6 Hazardous decomposition products

No decomposition may occur when the product is used for the intended purpose. Hazardous combustion products are listed in chapter 5.2





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11 Toxicological Information

11.1 Information on Toxcological Effects

Acute Toxicity

Not classified

Skin corrosion/irritation

Not classified

Serious eye damage/eye irritation

not classified

Respiratory or skin sensitation

Not classified

Summary of evaluation of the CMR properties

Not classified as germ cell mutagenic, carcinogenic nor as a reproductive toxicant

Specific target organ toxicity - single exposition

Not classified

Specific target organ toxicity - repeated exposition

Not classified

Aspiration hazard

Not classified

Symptoms related to the physical, chemical and toxicological characteristics of swallowed

No data available

If in eyes

Slightly irritant, but not relevant for classification.

If inhaled

Slightly irritant, but not relevant for classification.

If on skin

Slightly irritant, but not relevant for classification.

Other information

See chapter 4.3

12 Ecological information

12.1 Toxicity

Not classified as hazardous for the aquatic environment according to 1272/2008/EC.

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12.2 Process of degradability

Not applicable

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT- and vPvB-assessment

No data available

12.6 Other adverse effects

No data available

12.7 Other information

Do not dispose of the product uncharged in the environment.





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13 Waste Disposal Considerations

13.1 Waste treatment methods

Product

This product and its container must be treated as hazardous waste in compliance to local and national rules in suitable and tightly closed waste containers. Pay attention to corrosive effects.

Product residue and uncleaned container

Treat like product.

Cleaned packages

May added to general or industrial waste

Recommended cleaning agent

Water without any additives

14 Transport Information

14.1 Road / Rail / Inland waterway (ADR / RID/ADN)

No dangerous goods / not regulated

14.2 Maritime (IMDG)

No dangerous goods / not regulated

14.3 Air (ICAO / IATA)

No dangerous goods / not regulated

14.4 Packaging group

No dangerous goods / not regulated

14.5 Environmental hazards

No dangerous goods / not regulated

14.6 Special precautions for user

None

14.7 Transport in bulk according annex II of MARPOL 73/78 and the IBC-Code

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Not applicable, product is not intended to be transported in bulk





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15 Regulatory Information

15.1 Safety, health and environment regulations/legislation specific for the substance or mixture EU Regulations

Regulation 649/2012/EU concerning the export and import of hazardous chemicals (PIC)

None of the ingredients are listed. This Safety Data Sheet meets the requirements of regulation (EC) 1907/2006 (REACH).

Regulation1005/2009/EC on substances that deplete the ozon layer

None of the ingredients are listed

Restrictions according to REACH, Title VIII on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles

None

List of substances subject to authorization, REACH Annex XIV/SVHC candidate list

None of the ingredients are listed

Directive 2012/18/EU (Seveso III)

Not assigned

Regulation 166/2006/EC concerning the establishment of a European Pollutant Release and Transfer

Register (PRTR)

None of the ingredients are listed

Directive 2000/60/EC establishing a framework for Community action in the field of Water Policy (WFD)

None of the ingredients are listed

Regulation 98/2013/EU on the marketing and use of explosive precursers

None of the ingredients are listed.

Regulation 111/2005/EC on rules for the monitoring of trade between the Community and third countries in

drug precursers

None of the ingredients are listed.

Labelling concerning directive 1272/2008/EC

Refer to section 2.2

15.2 Chemical Safety Assesment

For this product, chemical safety assesments were not carried out.

15.3 Other information

No data available





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16 Other Information

16.1 Recommended restrictions of use

This product is only for use as in vitro diagnostics for the intented diagnostic purpose following strictly the instructions for use.

16.2 Copyright

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You only may produce paper copies of this safety data sheet for your own internal purpose. Reprinting, also in extracts, is prohibited.

16.3 Disclaimer

The information in this safety data sheet describes only the safety requirements of the product. It was recorded in all conscience and represents our knowledge on the present day. The information provided in this data sheet is intended to give you advice about the safe handling, store, processing, transport and disposal of the product and must not transferred to any other product. In case of mixing the product with any other substances or mixtures or processing to other products, this data sheet will lose its validation and the information is invalid for the new made-up material. This material safety data sheet will not suspend your own responsibility for the use and handling of the product. We take no responsibility for and are not liable for any defects, damages or losses which may occur by using the product. We refer explicitly to our terms of condition.

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16.4 Changes in Previous Editions

None