

# Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 14.10.2020

Version number 4

Revision: 17.12.2015

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

### 1.1 Product identifier

Trade name: **VitaFast® Vitamin B12 Assay Medium**

Article number: P1002M

### 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: CHEMTREC (worldwide): +1 703-741-5970 / 1-800-424-9300

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is not classified, according to the CLP regulation.

### 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void

Hazard pictograms Void

Signal word Void

Hazard statements Void

### 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 of substances with nonhazardous additions.

Dangerous components: Void

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: No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaints.

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

After eye contact: Rinse opened eye for several minutes under running water.

After swallowing: If symptoms persist consult doctor.

### 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

### 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

**Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

### 5.2 Special hazards arising from the substance or mixture

No further relevant information available.

### 5.3 Advice for firefighters

**Protective equipment:** No special measures required.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing.

**6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.**6.3 Methods and material for containment and cleaning up:** Pick up mechanically.

### 6.4 Reference to other sections

No dangerous substances are released.

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** No special measures required.**Information about fire - and explosion protection:** No special measures required.

### 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:** None.**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.

### 8.1 Control parameters

**Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

**Additional information:** The lists valid during the making were used as basis.

### 8.2 Exposure controls

**Personal protective equipment:****General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

**Respiratory protection:** Not required.**Protection of hands:**

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

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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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:**

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

**As protection from splashes gloves made of the following materials are suitable:**

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

**Eye protection:** Safety glasses

### SECTION 9: Physical and chemical properties

**9.1 Information on basic physical and chemical properties**
**General Information**
**Appearance:**

<b>Form:</b>	Solid
<b>Colour:</b>	Various colours
<b>Odour:</b>	Characteristic
<b>Odour threshold:</b>	Not determined.

**pH-value:** Not applicable.

**Change in condition**

<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	Undetermined.

**Flash point:** Not applicable.

**Flammability (solid, gas):** Not determined.

**Decomposition temperature:** Not determined.

**Auto-ignition temperature:** Product is not selfigniting.

**Explosive properties:** Product does not present an explosion hazard.

**Explosion limits:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

**Vapour pressure:** Not applicable.

<b>Density:</b>	Not determined.
<b>Relative density</b>	Not determined.
<b>Vapour density</b>	Not applicable.
<b>Evaporation rate</b>	Not applicable.

**Solubility in / Miscibility with water:** Soluble.

**Partition coefficient: n-octanol/water:** Not determined.

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**Viscosity:****Dynamic:**

Not applicable.

**Kinematic:**

Not applicable.

**Solvent content:****Solids content:**

99.7 %

**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.

### SECTION 11: Toxicological information

**11.1 Information on toxicological effects****Acute toxicity** Based on available data, the classification criteria are not met.**LD/LC50 values relevant for classification:****50-99-7 glucose**

Oral LD50 25,800 mg/kg (rat)

**127-09-3 sodium acetate**

Oral LD50 3,530 mg/kg (rat)

**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** Based on available data, the classification criteria are not met.**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.

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**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** Disposal must be made according to official regulations.

**Uncleaned packaging:**
**Recommendation:** Disposal must be made according to official regulations.

**Recommended cleansing agents:** Water, if necessary together with cleansing agents.

**SECTION 14: Transport information**
**14.1 UN-Number**
**ADR, ADN, IMDG, IATA** Void

**14.2 UN proper shipping name**
**ADR, ADN, IMDG, IATA** Void

**14.3 Transport hazard class(es)**
**ADR, ADN, IMDG, IATA**  
**Class** Void

**14.4 Packing group**
**ADR, IMDG, IATA** Void

**14.5 Environmental hazards:**
**Marine pollutant:** No

**14.6 Special precautions for user**

Not applicable.

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

Not applicable.

**Transport/Additional information:**

Not dangerous according to the above specifications.

**UN "Model Regulation":**

Void

**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** None of the ingredients is listed.

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**DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

**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.

**Department issuing SDS:** QS 0049-6151-8102-0**Contact:** QS 0049-6151-8102-0**Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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

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

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