

# Safety data sheet

## according to 1907/2006/EC, Article 31



Printing date 06.02.2018

Version number 6

Revision: 06.02.2018

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

#### 1.1 Product identifier

**Trade name:** RIDA qLine® Allergy Conjugate

**Article number:** 3068K01

#### 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



GHS08 health hazard

Repr. 1B H360D May damage the unborn child.

#### 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** GHS08

**Signal word** Danger

**Hazard statements**

H360D May damage the unborn child.

**Precautionary statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

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: 872-50-4	N-methyl-2-pyrrolidone	1-2.5%
EINECS: 212-828-1	Repr. 1B, H360D Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

##### SVHC

872-50-4	N-methyl-2-pyrrolidone
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**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

**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.

## 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:

Dilute with plenty of water.

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.

### 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

Open and handle receptacle with care.

**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.

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### 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:**

##### 872-50-4 N-methyl-2-pyrrolidone

WEL	Short-term value: 80 mg/m <sup>3</sup> , 20 ppm
	Long-term value: 40 mg/m <sup>3</sup> , 10 ppm
	Sk

**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.

Wash hands before breaks and at the end of work.

**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:  $\geq 0.11$  mm

Value for the permeation: Level  $\leq 480$

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

Nitrile rubber, NBR

Recommended thickness of the material:  $\geq 0.11$  mm

Value for the permeation: Level  $\leq 480$

**Eye protection:**



Tightly sealed goggles

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

##### General Information

##### Appearance:

Form:	Fluid
Colour:	White
Odour:	Characteristic
Odour threshold:	Not determined.

pH-value at 20 °C:	3.8
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##### Change in condition

Melting point/freezing point:	0 °C
Initial boiling point and boiling range:	100 °C

Flash point:	Not applicable.
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Flammability (solid, gas):	Not applicable.
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Decomposition temperature:	Not determined.
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Auto-ignition temperature:	Product is not selfigniting.
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Explosive properties:	Product does not present an explosion hazard.
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##### Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

Vapour pressure at 20 °C:	23 hPa
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Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

##### Solubility in / Miscibility with water:

Fully miscible.

Partition coefficient: n-octanol/water:	Not determined.
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##### Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

##### Solvent content:

Organic solvents:	2.0 %
Water:	93.1 %

Solids content:	0.0 %
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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.

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**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:

##### 872-50-4 N-methyl-2-pyrrolidone

Oral	LD50	3,914 mg/kg (rat)
Dermal	LD50	8,000 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

May damage the unborn child.

**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.

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

### SECTION 14: Transport information

<b>14.1 UN-Number</b> ADR, ADN, IMDG, IATA	Void
<b>14.2 UN proper shipping name</b> ADR, ADN, IMDG, IATA	Void
<b>14.3 Transport hazard class(es)</b> ADR, ADN, IMDG, IATA Class	Void
<b>14.4 Packing group</b> ADR, IMDG, IATA	Void
<b>14.5 Environmental hazards:</b> Marine pollutant:	No
<b>14.6 Special precautions for user</b>	Not applicable.
<b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
<b>Transport/Additional information:</b>	Not dangerous according to the above specifications.
<b>UN "Model Regulation":</b>	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.

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

National regulations:

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

**Other regulations, limitations and prohibitive regulations**

**Substances of very high concern (SVHC) according to REACH, Article 57**

872-50-4 N-methyl-2-pyrrolidone

**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**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H360D May damage the unborn child.

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**Department issuing SDS:** 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

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Repr. 1B: Reproductive toxicity – Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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

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