

Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 25.09.2018

Version number 3

Revision: 25.09.2018

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

1.1 Product identifier

Trade name: RIDASCREEN® TDM Substrate

Article number: 3099V01

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-determining components of labelling:

N-methyl-2-pyrrolidone

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	2.5-5%
EINECS: 212-828-1	Repr. 1B, H360D Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

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SVHC

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

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.

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

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 ³ , 20 ppm
	Long-term value: 40 mg/m ³ , 10 ppm
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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.

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: ≥ 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

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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:	Light blue
Odour:	Undistinguishable.
Odour threshold:	Not determined.

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

Melting point/freezing point:	Undetermined.
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.
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Partition coefficient: n-octanol/water:	Not determined.
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Viscosity:

Dynamic:	Not determined.
Kinematic:	Not determined.

Solvent content:

Organic solvents:	4.9 %
Water:	89.8 %

Solids content:	0.1 %
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9.2 Other information	No further relevant information available.
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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:** Not hazardous for water.**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.**Recommended cleansing agents:** Water, if necessary together with cleansing agents.

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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:	Not applicable.
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.

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 30, 71

National regulations:

Waterhazard class: Generally not 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.

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)

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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

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