

Printing date 11.05.2022 Version number 7.0 Revision: 20.12.2021

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

1.1 Product identifier

Trade name: <u>RIDASCREEN® Substrate</u>
Article number: 3019V01, 3019V01-VK

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: e-mail: info@r-biopharm.de

1.4 Emergency telephone number:

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

CHEMTREC (United Kingdom): 44-870-8200418 and 44-2038073798 (toll free)

For additional worldwide local emergency numbers refer to section 16.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture Classification according to Regulation (EC) No 1272/2008



Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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 GHS07

Signal word Warning

Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements

P264 Wash thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

P332+P313 If skin irritation occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

P337+P313 If eye irritation persists: Get medical advice/attention.

Additional information:

EUH208 Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

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vPvB: Not applicable.

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SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Mixture: consisting of the following components.

Dangerous components:			
CAS: 616-45-5 EINECS: 210-483-1	2-pyrrolidone	10-<15%	
	Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319		
CAS: 872-50-4 EINECS: 212-828-1	N-methyl-2-pyrrolidone	0.1-<0.3%	
	 Repr. 1B, H360D Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 		
CAS: 55965-84-9	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	<0.1%	
	 Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330 Skin Corr. 1C, H314; Eye Dam. 1, H318 Aquatic Acute 1, H400; Aquatic Chronic 1, H410 		
	Š Skin Sens. 1A, H317		

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

General information: Immediately remove any clothing soiled by the product.

After inhalation: 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. If symptoms persist, 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.

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.

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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).

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.

No special precautions are necessary if used correctly.

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: Keep container tightly sealed.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Additional information about design of technical facilities: No further data; see item 7.

Ingredients with limit values that require monitoring at the workplace:

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

WEL Short-term value: 80 mg/m³, 20 ppm Long-term value: 40 mg/m³, 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.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Respiratory protection: Not required.

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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 trough 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
Colour: Colourless
Odour: Characteristic
Odour threshold: Not determined.

pH-value at 20 °C: 4.1-4.6

Change in condition

Melting point/freezing point: 0 $^{\circ}$ C Initial boiling point and boiling range: 100 $^{\circ}$ C

Flash point: 138 °C

Flammability (solid, gas): Not applicable.

Ignition temperature: 240 °C

Decomposition temperature: Not determined.

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Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits: Lower: Upper:	Not determined. Not determined.
Vapour pressure at 20 °C:	23 hPa
Density at 20 °C: Relative density Vapour density Evaporation rate	0.99972 g/cm³ Not determined. Not determined. Not determined.
Solubility in / Miscibility with water:	Fully miscible.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity: Dynamic: Kinematic:	Not determined. Not determined.
Solvent content: Organic solvents: Water:	0.1 % 89.9 %
Solids content:	10.0 %
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:

616-45-5 2-pyrrolidone

Oral LD50 328 mg/kg (rat)

Primary irritant effect:

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

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Respiratory or skin sensitisation Based on available data, the classification criteria are not met. **Additional toxicological information:**

CMR effects (carcinogenity, 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.

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.

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

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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 I of Marpol and the IBC Code	l 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.

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

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H330 Fatal if inhaled.

H335 May cause respiratory irritation.

H360D May damage the unborn child.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

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

Contact: QS 0049-6151-8102-0

Worldwide local emergency numbers

Argentina Spanish Local (City) Buenos Aires Americas 54-1159839431

Australia English Local (City) Sydney Oceania 61-290372994

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Austria German Local (City) Vienna Europe 43-13649237

Belgium French Local (City) Brussels Europe 32-28083237

Brazil Portuguese Local (City) Rio De Janeiro Americas 55-2139581449

Brazil Portuguese Local (City) Sao Paulo Americas 55-1143491359

Brazil - Toll Free Portuguese Toll free Mobile-Enabled Americas 0800 892 0479

Bulgaria Bulgarian Local (City) Plovdiv Europe 359-32570104

Cayman Islands English Local (National) Americas 345-749-8392

Chile Spanish Local (City) Santiago Américas 56 2 2581 4934

China Mandarin Local (National) Asia 4001-204937

Colombia Spanish Toll Free Americas 01800-710-2151

Costa Rica Spanish Local (National) Americas 506-40003869

Croatia Croatian Local (City) Zagreb Europe 385-17776920

Czech Republic Czech Local (City) Prague Europe 420-228880039

Denmark Danish Local (National) Europe 45-69918573

Dominican Republic Spanish Local (City) Santo Domingo Americas (829) 956-7588

El Salvador Spanish Local (City) San Salvador Americas 503 2136 7633

Estonia Estonian Local (National) Europe 372-6681294

Finland Finnish Local (City) Helsinki Europe 358-942419014

France French National Europe 33-975181407

Germany German Local (City) Frankfurt Europe 49-69643508409 0800-181-7059

Greece Greek Local (City) Athens Europe 30-2111768478

Grenada English Local (City) St George Americas 1 (473) 230-0165

Guinea French Americas 224 660 71 03 00

Hong Kong Toll Free Asia 800-968-793

Hungary Hungarian Local (City) Budapest Europe 36-18088425

Iceland Icelandic Local (City) Reykjavik Europe 354 539 0655

India Hindi, Bengali, English Asia 000-800-100-7141

Indonesia Indonesian Toll Free Asia 001-803-017-9114

Ireland English Local (City) Dublin Europe 353-19014670

Israel Hebrew Local (City) Tel Aviv Asia 972-37630639

Italy Italian Local (City) Milan Europe 39-0245557031 800-789-767

Japan Japanese Local (City) Tokyo Asia 81-345209637

Latvia Latvian Lettish Local (City) Riga Europe 371-66165504

Lithuania Lithuanian Local (City) Vilnius Europe 370-52140238

Luxembourg French and German Europe 352-20202416

Macedonia Macedonian Local (City) Skopje Europe 389 2 551 7456

Malaysia Malay Local (City) Kuala Lumpur Asia 60-39212579 41-800-815-308

Mexico Spanish Americas 01-800-681-9531

Netherlands Dutch Europe 31-858880596

New Zealand English Local (City) Auckland Oceania 64-98010034

Nigeria Hausa Local (City) Lagos Europe 234 1 227 8883

Panama Spanish Local (National) Americas 507-8322475

Peru Spanish Local (City) Lima Americas 51-17071295

Philippines Tagalog Local (City) Manila Asia 1-800-1-116-1020

Poland Polish Local (City) Warsaw Europe 48-223988029

Portugal Portuguese Local (National) Europe 351-308801773

Romania Romanian Local (National) Europe 40-37-6300026

Russia RussianToll Free Mobile-Enabled Asia 8-800-100-6346

Saudi Arabia Arabic and English CHEMTREC DID Only Asia 966-8111095861

Singapore English and Mandarin Asia 65-31581349 or 800-101-2201

Slovakia Slovak Local (City) Bratislava Europe 421-233057972

Slovenia Slovenian Local (City) Ljubljana Europe 38-618888016

South Africa English Toll Free Africa 0-800-983-611

South Korea Korean Toll Free Asia 003-0813-2549 and 080-822-1374

Spain Spanish Local (City) Barcelona Europe 34-931768545 and 900-868538

Sweden Swedish Local (City) Stockholm Europe 46-852503403

Switzerland German and French and Italian Zurich Europe 41-435082011

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Taiwan Mandarin Local (City) Taipei Asia 886-2-7741-4207 and 00801-14-8954

Thailand Thai Toll Free Asia 01-800-13-203-9987

Trinidad and Tobago English Local (National) Americas 1-868-224-5716

Turkey Turkish Local (City) Istanbul Europe 90-212-7055340

Ukraine Ukrainian Europe 380-947101374

United Kingdom English Local (City) London Europe 44-870-8200418 and 44-2038073798

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)

ICAO: International Civil Aviation Organisation

ADR: Accord relatif au transport international 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

Acute Tox. 3: Acute toxicity - Category 3

Acute Tox. 4: Acute toxicity - Category 4

Acute Tox. 2: Acute toxicity – Category 2 Skin Corr. 1C: Skin corrosion/irritation – Category 1C

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

Eye Dam. 1: Serious eye damage/eye irritation - Category 1 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1A: Skin sensitisation – Category 1A Repr. 1B: Reproductive toxicity – Category 1B

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

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

* Data compared to the previous version altered.

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