

Safety Information
Human CGRP ELISA

Revision Date: 10.2.2020

The RA19021R Human CGRP ELISA kit has been developed and validated to measure Calcitonin Gene Related Peptide (CGRP) in serum, plasma, whole blood, CSF and nervous tissue extracts.

For professional use only. Users should have a thorough understanding of the Product Data Sheet prior to their use of this kit.

Kit Components:

- A) Antibody Coated Microtiter Strips
- B) CGRP Standard
- C) CGRP Quality Control
- D) CGRP Tracer
- E) EIA Buffer
- F) Wash Buffer
- G) Tween 20
- H) Substrate Solution (Ellman's Reagent)

Components B) – E) and component H) are hazardous mixtures according to CLP Regulation (EC) as amended. Safety Data Sheets according to actual Regulations (EC/EU) are attached.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Standard (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: CGRP Standard (RA19021R Kit)

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

Assay component – CGRP standard.

1.3 Details of the supplier of the safety data sheet

BioVendor - Laboratorní medicína a.s.
Karásek 1767/1
621 00 Brno
Czech Republic
Identification number: 63471507

Tel: +420 549 124 185

E-mail: info@biovendor.com

1.4 Emergency telephone number

Toxicology information centre, Na Bojišti 1, 128 21 Prague, Czech Republic, **Tel: +420 224 919 293 or +420 224 915 402 (non-stop service).**

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation 1272/2008/EC:

Reproductive toxicity 1B, H360D

Aquatic Chronic 3, H412

2.2 Label elements

Hazard pictogram:



Signal word:

Danger

Hazard statements:

H360D May damage the unborn child.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P201 Obtain special instructions before use.

P273 Avoid release to the environment.

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

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

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Standard (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

2.3 Other hazards

Results of PBT and vPvB assessment:

PBT: Not applicable.

vPvB: Not applicable.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures

Ingredient	Conc. in w/w%	EINECS	CAS-Nr.
N,N-dimethylformamide	0.1– <2.5	200-679-5	68-12-2

Classification according to regulation 1272/2008/EC:

Flam. Liq. 3, H226; Repr. 1B, H360D; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319

Ingredient	Conc. in w/w%	EINECS	CAS-Nr.
sodium azide	0.25– <2.5	247-852-1	26628-22-8

Classification according to regulation 1272/2008/EC:

Acute Tox. 2, H300; STOT RE 2, H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410

For full text of H-phrases see 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: Generally, the product does not irritate the skin.

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

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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

Not required.

6.2 Environmental precautions:

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/ surface or ground water.

CGRP Standard (RA19021R Kit)

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Supersedes date:

6.3 Methods and material for containment and cleaning up:

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

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

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.

Recommended storage temperature: -20°C

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:

CAS: 68-12-2, N,N-dimethylformamide

WEL Short-term value: 30 mg/m³, 10 ppm

Long-term value: 15 mg/m³, 5 ppm

Sk

CAS: 26628-22-8, sodium azide

WEL Short-term value: 0.3 mg/m³

Long-term value: 0.1 mg/m³

(as NaN₃), 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:

Wash hands before breaks and at the end of work.

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. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. 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 cannot be calculated in advance and has therefore to be

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CGRP Standard (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

Eye protection: checked prior to the application. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
Not required.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form:	Solid
Colour:	White
Odour:	Uncharacteristic.
Odour threshold:	Not determined.
pH-value:	Not applicable.
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gas):	Not determined.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not self-igniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not applicable.
Density:	Not determined.
Relative density:	Not determined.
Vapour density:	Not applicable.
Evaporation rate:	Not applicable.
Solubility in / Miscibility with water:	Soluble.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.

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.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Standard (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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:

CAS: 68-12-2, N,N-dimethylformamide

Oral LD50 2,800 mg/kg (rat)

Dermal LD50 1,500 mg/kg (rabbit)

Inhalative LC50 4h 9-15 mg/l (rat)

CAS: 26628-22-8, sodium azide

Oral LD50 27 mg/kg (rat)

Dermal LD50 20 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:

CAS: 68-12-2, N,N-dimethylformamide

LC50 96h >500 mg/l (Desmodesmus subspicatus)

6,700-7,500 mg/l (Lepomis macrochirus)

9,000-13,000 mg/l (Oncorhynchus mykiss)

10,400-10,800 mg/l (Pimephales promelas)

15,700 mg/l (Daphnia magna)

EC50 48h

CAS: 26628-22-8 sodium azide

EC50 96h (static) 0.35 mg/l (Pseudokirchneriella subcapitata)

LC50 96h 5.46 mg/l (Pimephales promelas)

CGRP Standard (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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.

Ecotoxic effects:

Remark: Harmful to fish

Additional ecological information:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system. Harmful to aquatic organisms.

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.

European waste catalogue

HP 6 Acute Toxicity

HP 10 Toxic for reproduction

HP 14 Ecotoxic

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 not regulated

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA not regulated

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA Class not regulated

14.4 Packing group

ADR, IMDG, IATA not regulated

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user

Not applicable.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Standard (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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

Not applicable.

Transport/Additional information:

IATA Remarks: When sold in quantities of less than or equal to 1mL or 1g with an Excepted Quantity Code of E1, E2, E3, E4 or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore, packaging does not have to be labeled as Dangerous Goods/Excepted Quantity

SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation of the European Parliament and the Council (EC) No. 1907/2006 (REACH).
Regulation of the European Parliament and the Council (EC) No. 1272/2008 (CLP).
Commission Regulation (EU) No. 830/2015.

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

Substances of very high concern (SVHC) according to REACH, Article 57: CAS: 68-12-2,
N,N-dimethylformamide

15.2 Chemical safety assessment

Chemical safety assessment has not been carried out.

SECTION 16 OTHER INFORMATION

Date of issue: 10.2.2020

Revision notes:

Full text of H-phrases:

H226 Flammable liquid and vapour.

H300 Fatal if swallowed.

H312 Harmful in contact with skin.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H360D May damage the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Advice on training

Workers shall receive appropriate training to acquaint them with the recommended use, mandatory protective equipment, first aid measures and banned manners of handling the mixture.

Note:

The safety data sheet contains data necessary for ensuring occupational health and safety and protection of the environment. The given data correspond to the current state of knowledge and experience and comply with valid legal regulations. The data cannot be considered a guarantee that the specific use of the product will be appropriate.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Quality Control (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: CGRP Quality Control (RA19021R Kit)

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

Assay component – Quality control sample.

1.3 Details of the supplier of the safety data sheet

BioVendor - Laboratorní medicína a.s.
Karásek 1767/1
621 00 Brno
Czech Republic
Identification number: 63471507

Tel: +420 549 124 185

E-mail: info@biovendor.com

1.4 Emergency telephone number

Toxicology information centre, Na Bojišti 1, 128 21 Prague, Czech Republic, **Tel: +420 224 919 293 or +420 224 915 402 (non-stop service).**

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation 1272/2008/EC:

Reproductive toxicity 1B, H360D

Aquatic Chronic 3, H412

2.2 Label elements

Hazard pictogram:



Signal word:

Danger

Hazard statements:

H360D May damage the unborn child.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P201 Obtain special instructions before use.

P273 Avoid release to the environment.

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

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

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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in accordance with Regulation (EC) No. 1907/2006 of the European Parliament and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Quality Control (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

2.3 Other hazards

Results of PBT and vPvB assessment:

PBT: Not applicable.

vPvB: Not applicable.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Mixtures

Ingredient	Conc. in w/w%	EINECS	CAS-Nr.
N,N-dimethylformamide	0.1– <2.5	200-679-5	68-12-2

Classification according to regulation 1272/2008/EC:

Flam. Liq. 3, H226; Repr. 1B, H360D; Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319

Ingredient	Conc. in w/w%	EINECS	CAS-Nr.
sodium azide	0.25– <2.5	247-852-1	26628-22-8

Classification according to regulation 1272/2008/EC:

Acute Tox. 2, H300; STOT RE 2, H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410

For full text of H-phrases see 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: Generally, the product does not irritate the skin.

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

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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

Not required.

6.2 Environmental precautions:

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/ surface or ground water.

CGRP Quality Control (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

6.3 Methods and material for containment and cleaning up:

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

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

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.

Recommended storage temperature: -20°C

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:

CAS: 68-12-2, N,N-dimethylformamide

WEL Short-term value: 30 mg/m³, 10 ppm

Long-term value: 15 mg/m³, 5 ppm

Sk

CAS: 26628-22-8, sodium azide

WEL Short-term value: 0.3 mg/m³

Long-term value: 0.1 mg/m³

(as NaN₃), 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:

Wash hands before breaks and at the end of work.

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. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. 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 cannot be calculated in advance and has therefore to be

MATERIAL SAFETY DATA SHEET

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CGRP Quality Control (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

Eye protection: checked prior to the application. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
Not required.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form:	Solid
Colour:	White
Odour:	Uncharacteristic.
Odour threshold:	Not determined.
pH-value:	Not applicable.
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gas):	Not determined.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not self-igniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not applicable.
Density:	Not determined.
Relative density:	Not determined.
Vapour density:	Not applicable.
Evaporation rate:	Not applicable.
Solubility in / Miscibility with water:	Soluble.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.

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.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Quality Control (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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:

CAS: 68-12-2, N,N-dimethylformamide

Oral LD50 2,800 mg/kg (rat)

Dermal LD50 1,500 mg/kg (rabbit)

Inhalative LC50 4h 9-15 mg/l (rat)

CAS: 26628-22-8, sodium azide

Oral LD50 27 mg/kg (rat)

Dermal LD50 20 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:

CAS: 68-12-2, N,N-dimethylformamide

LC50 96h >500 mg/l (Desmodesmus subspicatus)

6,700-7,500 mg/l (Lepomis macrochirus)

9,000-13,000 mg/l (Oncorhynchus mykiss)

10,400-10,800 mg/l (Pimephales promelas)

15,700 mg/l (Daphnia magna)

EC50 48h

CAS: 26628-22-8 sodium azide

EC50 96h (static) 0.35 mg/l (Pseudokirchneriella subcapitata)

LC50 96h 5.46 mg/l (Pimephales promelas)

CGRP Quality Control (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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.

Ecotoxic effects:

Remark: Harmful to fish

Additional ecological information:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system. Harmful to aquatic organisms.

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.

European waste catalogue

HP 6 Acute Toxicity

HP 10 Toxic for reproduction

HP 14 Ecotoxic

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 not regulated

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA not regulated

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA Class not regulated

14.4 Packing group

ADR, IMDG, IATA not regulated

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user

Not applicable.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Quality Control (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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

Not applicable.

Transport/Additional information:

IATA Remarks: When sold in quantities of less than or equal to 1mL or 1g with an Excepted Quantity Code of E1, E2, E3, E4 or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore, packaging does not have to be labeled as Dangerous Goods/Excepted Quantity

SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation of the European Parliament and the Council (EC) No. 1907/2006 (REACH).
Regulation of the European Parliament and the Council (EC) No. 1272/2008 (CLP).
Commission Regulation (EU) No. 830/2015.

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

Substances of very high concern (SVHC) according to REACH, Article 57: CAS: 68-12-2, N,N-dimethylformamide

15.2 Chemical safety assessment

Chemical safety assessment has not been carried out.

SECTION 16 OTHER INFORMATION

Date of issue: 10.2.2020

Revision notes:

Full text of H-phrases:

H226 Flammable liquid and vapour.

H300 Fatal if swallowed.

H312 Harmful in contact with skin.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H360D May damage the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Advice on training

Workers shall receive appropriate training to acquaint them with the recommended use, mandatory protective equipment, first aid measures and banned manners of handling the mixture.

Note:

The safety data sheet contains data necessary for ensuring occupational health and safety and protection of the environment. The given data correspond to the current state of knowledge and experience and comply with valid legal regulations. The data cannot be considered a guarantee that the specific use of the product will be appropriate.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Tracer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: CGRP Tracer (RA19021R Kit)

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

Assay component – tracer conjugate.

1.3 Details of the supplier of the safety data sheet

BioVendor - Laboratorní medicína a.s.
Karásek 1767/1
621 00 Brno
Czech Republic
Identification number: 63471507

Tel: +420 549 124 185

E-mail: info@biovendor.com

1.4 Emergency telephone number

Toxicology information centre, Na Bojišti 1, 128 21 Prague, Czech Republic, **Tel: +420 224 919 293 or +420 224 915 402 (non-stop service).**

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation 1272/2008/EC:

Aquatic Chronic 3, H412

2.2 Label elements

Hazard pictogram:

Void

Signal word:

Void

Hazard statements:

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P273 Avoid release to the environment.

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

3.1 Mixtures

Ingredient	Conc. in w/w%	EINECS	CAS-Nr.
sodium azide	0.25– <2.5	247-852-1	26628-22-8

Classification according to regulation 1272/2008/EC:

Acute Tox. 2, H300; STOT RE 2, H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410

For full text of H-phrases see section 16.

CGRP Tracer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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: Generally, the product does not irritate the skin.
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

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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

Not required.

6.2 Environmental precautions:

Inform respective authorities in case of seepage into water course or sewage system.
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

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 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

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.

Recommended storage temperature: -20°C

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Tracer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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:

CAS: 26628-22-8, sodium azide

WEL Short-term value: 0.3 mg/m³

Long-term value: 0.1 mg/m³

(as NaN₃), 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:

Wash hands before breaks and at the end of work.

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. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. 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 cannot be calculated in advance and has therefore to be checked prior to the application. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection: Not required.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form:	Solid
Colour:	Whitish
Odour:	Uncharacteristic.
Odour threshold:	Not determined.
pH-value:	Not applicable.
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	100°C
Flash point:	Not applicable.
Flammability (solid, gas):	Not determined.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not self-igniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not applicable.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Tracer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

Density:	Not determined.
Relative density:	Not determined.
Vapour density:	Not applicable.
Evaporation rate:	Not applicable.
Solubility in / Miscibility with water:	Soluble.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity: Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solvent content:	
Solids content:	97.5%

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:

CAS: 26628-22-8, sodium azide

Oral LD50 27 mg/kg (rat)
Dermal LD50 20 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.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Tracer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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:

CAS: 26628-22-8 sodium azide

EC50 96h (static)

0.35 mg/l (Pseudokirchneriella subcapitata)

LC50 96h

5.46 mg/l (Pimephales promelas)

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.

Ecotoxic effects:

Remark: Harmful to fish

Additional ecological information:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system. Harmful to aquatic organisms.

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.

European waste catalogue

HP 6 Acute Toxicity

HP 14 Ecotoxic

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Tracer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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 not regulated

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA not regulated

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA Class not regulated

14.4 Packing group

ADR, IMDG, IATA not regulated

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:

IATA Remarks: When sold in quantities of less than or equal to 1mL or 1g with an Excepted Quantity Code of E1, E2, E3, E4 or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore, packaging does not have to be labeled as Dangerous Goods/Excepted Quantity

SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation of the European Parliament and the Council (EC) No. 1907/2006 (REACH).
Regulation of the European Parliament and the Council (EC) No. 1272/2008 (CLP).
Commission Regulation (EU) No. 830/2015.

15.2 Chemical safety assessment

Chemical safety assessment has not been carried out.

SECTION 16 OTHER INFORMATION

Date of issue: 10.2.2020

Revision notes:

Full text of H-phrases:

H300 Fatal if swallowed.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

CGRP Tracer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

Advice on training

Workers shall receive appropriate training to acquaint them with the recommended use, mandatory protective equipment, first aid measures and banned manners of handling the mixture.

Note:

The safety data sheet contains data necessary for ensuring occupational health and safety and protection of the environment. The given data correspond to the current state of knowledge and experience and comply with valid legal regulations. The data cannot be considered a guarantee that the specific use of the product will be appropriate.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

EIA Buffer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: EIA Buffer (RA19021R Kit)

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

Assay component – dilution buffer.

1.3 Details of the supplier of the safety data sheet

BioVendor - Laboratorní medicína a.s.
Karásek 1767/1
621 00 Brno
Czech Republic
Identification number: 63471507

Tel: +420 549 124 185

E-mail: info@biovendor.com

1.4 Emergency telephone number

Toxicology information centre, Na Bojišti 1, 128 21 Prague, Czech Republic, **Tel: +420 224 919 293 or +420 224 915 402 (non-stop service).**

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation 1272/2008/EC:

Aquatic Chronic 3, H412

2.2 Label elements

Hazard pictogram:

Void

Signal word:

Void

Hazard statements:

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P273 Avoid release to the environment.

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

3.1 Mixtures

Ingredient	Conc. in w/w%	EINECS	CAS-Nr.
sodium azide	0.25– <2.5	247-852-1	26628-22-8

Classification according to regulation 1272/2008/EC:

Acute Tox. 2, H300; STOT RE 2, H373; Aquatic Acute 1, H400; Aquatic Chronic 1, H410

For full text of H-phrases see section 16.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

EIA Buffer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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: Generally, the product does not irritate the skin.
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

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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

Not required.

6.2 Environmental precautions:

Inform respective authorities in case of seepage into water course or sewage system.
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

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 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

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.

Recommended storage temperature: -20°C

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

EIA Buffer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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:

CAS: 26628-22-8, sodium azide

WEL Short-term value: 0.3 mg/m³

Long-term value: 0.1 mg/m³

(as NaN₃), 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:

Wash hands before breaks and at the end of work.

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. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. 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 cannot be calculated in advance and has therefore to be checked prior to the application. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection: Not required.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form:	Solid
Colour:	Whitish
Odour:	Uncharacteristic.
Odour threshold:	Not determined.
pH-value:	Not applicable.
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	1461°C
Flash point:	Not applicable.
Flammability (solid, gas):	Not determined.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not self-igniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not applicable.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
 and the Council (REACH) and Commission Regulation (EU) No. 830/2015

EIA Buffer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

Density:	Not determined.
Relative density:	Not determined.
Vapour density:	Not applicable.
Evaporation rate:	Not applicable.
Solubility in / Miscibility with water:	Soluble.
Partition coefficient:	
n-octanol/water:	Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solvent content:	
Solids content:	100.0%

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:

CAS: 26628-22-8, sodium azide

Oral LD50 27 mg/kg (rat)
 Dermal LD50 20 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.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

EIA Buffer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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:

CAS: 26628-22-8 sodium azide

EC50 96h (static)

0.35 mg/l (Pseudokirchneriella subcapitata)

LC50 96h

5.46 mg/l (Pimephales promelas)

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.

Ecotoxic effects:

Remark: Harmful to fish

Additional ecological information:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system. Harmful to aquatic organisms.

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.

European waste catalogue

HP 6 Acute Toxicity

HP 14 Ecotoxic

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

EIA Buffer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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 not regulated

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA not regulated

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA Class not regulated

14.4 Packing group

ADR, IMDG, IATA not regulated

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:

IATA Remarks: When sold in quantities of less than or equal to 1mL or 1g with an Excepted Quantity Code of E1, E2, E3, E4 or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore, packaging does not have to be labeled as Dangerous Goods/Excepted Quantity

SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation of the European Parliament and the Council (EC) No. 1907/2006 (REACH).
Regulation of the European Parliament and the Council (EC) No. 1272/2008 (CLP).
Commission Regulation (EU) No. 830/2015.

15.2 Chemical safety assessment

Chemical safety assessment has not been carried out.

SECTION 16 OTHER INFORMATION

Date of issue: 10.2.2020

Revision notes:

Full text of H-phrases:

H300 Fatal if swallowed.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

EIA Buffer (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

Advice on training

Workers shall receive appropriate training to acquaint them with the recommended use, mandatory protective equipment, first aid measures and banned manners of handling the mixture.

Note:

The safety data sheet contains data necessary for ensuring occupational health and safety and protection of the environment. The given data correspond to the current state of knowledge and experience and comply with valid legal regulations. The data cannot be considered a guarantee that the specific use of the product will be appropriate.

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament
and the Council (REACH) and Commission Regulation (EU) No. 830/2015

Substrate Solution (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: Substrate Solution (RA19021R Kit)

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

Assay component – Ellman´s reagent.

1.3 Details of the supplier of the safety data sheet

BioVendor - Laboratorní medicína a.s.

Karásek 1767/1

621 00 Brno

Czech Republic

Identification number: 63471507

Tel: +420 549 124 185

E-mail: info@biovendor.com

1.4 Emergency telephone number

Toxicology information centre, Na Bojišti 1, 128 21 Prague, Czech Republic, **Tel: +420 224 919 293 or +420 224 915 402 (non-stop service).**

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation 1272/2008/EC:

Acute Tox. 4, H302

Skin Irrit. 2, H315

Eye Irrit. 2, H319

2.2 Label elements

Hazard pictogram:



Signal word:

Warning

Hazard-determining components of labelling:

2-acetylthioethyltrimethylammonium iodide

Hazard statements:

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Precautionary statements:

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.

P321 Specific treatment (see on this label).

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

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

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament and the Council (REACH) and Commission Regulation (EU) No. 830/2015

Substrate Solution (RA19021R Kit)

Date of issue: 10.2.2020

Supersedes date:

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

3.1 Mixtures

Ingredient	Conc. in w/w%	EINECS	CAS-Nr.
2-acetylthioethyltrimethylammonium iodide	2.5 – <10	217-472-0	1866-15-5

Classification according to regulation 1272/2008/EC:

Acute Tox. 3, H301; Acute Tox. 3, H311; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335

Ingredient	Conc. in w/w%	EINECS	CAS-Nr.
3,3'-dithiobis[6-nitrobenzoic] acid	2.5 – <10	200-714-4	69-78-3

Classification according to regulation 1272/2008/EC:

Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335

For full text of H-phrases see section 16.

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

General information:

Symptoms of poisoning may even occur after several hours, therefore medical observation for at least 48 hours after the accident.

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: Call for a doctor immediately.

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

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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

Not required.

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

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 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

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.

Recommended storage temperature: -20°C

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:

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.

Protection of hands:

Protective gloves. 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. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. The selection of the suitable gloves

MATERIAL SAFETY DATA SHEET

in accordance with Regulation (EC) No. 1907/2006 of the European Parliament and the Council (REACH) and Commission Regulation (EU) No. 830/2015

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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 cannot be calculated in advance and has therefore to be checked prior to the application. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection: Tightly sealed goggles

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form:	Solid
Colour:	Light yellow
Odour:	Odourless
Odour threshold:	Not determined.
pH-value:	Not applicable.
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	1461°C
Flash point:	Not applicable.
Flammability (solid, gas):	Not determined.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not self-igniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not applicable.
Density:	Not determined.
Relative density:	Not determined.
Vapour density:	Not applicable.
Evaporation rate:	Not applicable.
Solubility in / Miscibility with water:	Soluble.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solvent content:	
Solids content:	100%

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.

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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: Harmful if swallowed

LD/LC50 values relevant for classification:

CAS: 1866-15-5, 2-acetylthioethyltrimethylammonium iodide

Oral LD50 100 mg/kg (rat)

Dermal LD50 500 mg/kg (guinea pig)

CAS: 69-78-3, 3,3'-dithiobis[6-nitrobenzoic] acid

LD50 Intraperitoneal 2080 mg/kg (mouse)

Primary irritant effect:

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Causes serious eye damage.

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.

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12.4 Mobility in soil

No further relevant information available.

Additional ecological information:

Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground.

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.

European waste catalogue

HP 6 Acute Toxicity

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 not regulated

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA not regulated

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA Class not regulated

14.4 Packing group

ADR, IMDG, IATA not regulated

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:

IATA Remarks: When sold in quantities of less than or equal to 1mL or 1g with an Excepted Quantity Code of E1, E2, E3, E4 or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore, packaging does not have to be labeled as Dangerous Goods/Excepted Quantity

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SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation of the European Parliament and the Council (EC) No. 1907/2006 (REACH).
Regulation of the European Parliament and the Council (EC) No. 1272/2008 (CLP).
Commission Regulation (EU) No. 830/2015.

15.2 Chemical safety assessment

Chemical safety assessment has not been carried out.

SECTION 16 OTHER INFORMATION

Date of issue: 10.2.2020

Revision notes:

Full text of H-phrases:

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Advice on training

Workers shall receive appropriate training to acquaint them with the recommended use, mandatory protective equipment, first aid measures and banned manners of handling the mixture.

Note:

The safety data sheet contains data necessary for ensuring occupational health and safety and protection of the environment. The given data correspond to the current state of knowledge and experience and comply with valid legal regulations. The data cannot be considered a guarantee that the specific use of the product will be appropriate.