

Safety Information

Histamine ELISA

Revision Date: 16.1.2018

The RA19008R Histamine ELISA kit is a competitive assay that may be used to measure histamine in samples such as plasma, urine, culture supernatants as well as liquid (e.g. broncho-alveolar lavage fluids) or solid (brain, nervous tissues) biological samples after extraction.

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) Conjugate Solution (Histamine tracer)
- C) Histamine Standard
- D) Derivatization reagent
- E) Derivatization buffer
- F) Quality Control sample
- G) Dilution Buffer (EIA buffer)
- H) Wash Solution Concentrate
- I) Substrate Solution (Ellman's reagent)
- J) Tween 20

Components B), D) and I) are hazardous mixtures according to CLP Regulation (EC) as amended. Safety Data Sheets according to actual Regulations (EC/EU) are attached. Safety Data Sheet for component E) according to actual Regulations (EC/EU) is attached too.



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

Conjugate Solution (RA19008R Kit)

Date of issue: 16.1.2018 Supersedes date:

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

1.1 Product identifier

Trade name: Conjugate Solution (RA19008R Kit)

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

Assay component - Histamine tracer.

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. 3, H311 Aquatic Chronic 2, H411 Acute Tox. 4, H302

2.2 Label elements

Hazard pictogram:





Signal word:

Danger

Hazard-determining components of labelling:

sodium azide

Hazard statements:

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

P280 Wear protective gloves / protective clothing.

P273 Avoid release to the environment.

P321 Specific treatment (see on this label).

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

P405 Store locked up.

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



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

Conjugate Solution (RA19008R Kit)

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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. sodium azide 2.5–<10 247-852-1 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

General information:

Immediately remove any clothing soiled by the product.

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

In case of irregular breathing or respiratory arrest provide artificial respiration.

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. Then

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.

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.



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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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

Thorough dedusting.

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: 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:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

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 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



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

Conjugate Solution (RA19008R Kit)

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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:

Flammability (solid, gas):

Decomposition temperature:

Not applicable.

Not determined.

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:

Organic solvents: 0.0% Solids content: 99.5%

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.



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

Conjugate Solution (RA19008R Kit)

Date of issue: 16.1.2018 Supersedes date:

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.

Toxic in contact with skin.

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.

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:

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.



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12.4 Mobility in soil

No further relevant information available.

Ecotoxic effects: Remark: Toxic for fish

Additional ecological information:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system. Also poisonous for fish and plankton in water bodies.

Toxic for 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**

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 UN2025

14.2 UN proper shipping name

ADR UN2025 MERCURY COMPOUND, SOLID, N.O.S.

(SODIUM AZIDE), ENVIRONMENTALLY

HAZARDOUS

MERCURY COMPOUND, SOLID, N.O.S. (SODIUM **IMDG**

AZIDE), MARINE POLLUTANT

IATA MERCURY COMPOUND, SOLID, N.O.S. (SODIUM

AZIDE)

14.3 Transport hazard class(es)

ADR, IMDG 6.1 Toxic substances (label 6.1) IATA 6.1 Toxic substances (label 6.1)

14.4 Packing group

ADR, IMDG, IATA Ш

14.5 Environmental hazards:

Product contains environmentally hazardous substances: sodium azide

Marine pollutant: Symbol (fish and tree) Special marking (ADR): Symbol (fish and tree).



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14.6 Special precautions for user

Danger code (Kemler): 60 EMS Number: F-A,S-A

Segregation groups: Heavy metals and their salts (including their

organometallic compounds), mercury and mercury

compounds.

Stowage Category:

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

Not applicable.

Transport/Additional information:

ADR

Limited quantities (LQ): 5 kg
Excepted quantities (EQ): Code: E1
Maximum net quantity per inner packaging: 30 g
Maximum net quantity per outer packaging: 1000 g
Transport category: 2
Tunnel restriction code: E

IMDG

Limited quantities (LQ): 5 kg
Excepted quantities (EQ): Code: E1
Maximum net quantity per inner packaging: 30 g
Maximum net quantity per outer packaging: 1000 g

IATA

Excepted quantities (EQ):

Maximum net quantity per inner packaging:

Maximum net quantity per outer packaging:

1000 g

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 Quantites 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.

Seveso category: E2 Hazardous to the Aquatic Environment

Qualifying quantity (tonnes) for the application of lower-tier requirements: 200 t Qualifying quantity (tonnes) for the application of upper-tier requirements: 500 t

15.2 Chemical safety assessment

Chemical safety assessment has not been carried out.



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Conjugate Solution (RA19008R Kit)

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SECTION 16 OTHER INFORMATION

Date of issue: 16.1.2018

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.

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.



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

Derivatization reagent (RA19008R Kit)

Date of issue: 16.1.2018 Supersedes date:

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

1.1 Product identifier

Trade name: Derivatization reagent (RA19008R Kit)

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

Assay component - Histamine derivatization 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:

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

2.2 Label elements

Hazard pictogram:



Signal word:

Warning

Hazard-determining components of labelling:

Bolton-Hunter reagent precursor

Hazard statements:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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).

P405 Store locked up.



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

Derivatization reagent (RA19008R Kit)

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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.

Bolton-Hunter reagent precursor

— 251-818-1 34071-95-9

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 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

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:

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

6.3 Methods and material for containment and cleaning up:

Ensure adequate ventilation.

Dispose contaminated material as waste according to item 13.



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

Derivatization reagent (RA19008R Kit)

Date of issue: 16.1.2018 Supersedes date:

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

Ensure good ventilation/exhaustion at the workplace.

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:

Not required.

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: In case of brief exposure or low pollution use respiratory filter device.

In case of intensive or longer exposure use self-contained

respiratory protective device.

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 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. 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



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Derivatization reagent (RA19008R Kit)

Date of issue: 16.1.2018 Supersedes date:

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form: Powder Colour: Beige

Odour:
Odour threshold:
PH-value:
Not applicable.
Melting point/freezing point:
Initial boiling point and boiling range:
Flash point:
Uncharacteristic.
Not determined.
132–133°C
Undetermined.
Not applicable.

Flammability (solid, gas): Product is not flammable.

Decomposition temperature: Not determined. Auto-ignition temperature: Not determined.

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: Insoluble.

Partition coefficient:

n-octanol/water: Not determined.

Viscosity:

Dynamic: Not applicable. Kinematic: Not applicable.

Solvent content:

Organic solvents: 0.0% 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.

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.



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

Derivatization reagent (RA19008R Kit)

Date of issue: 16.1.2018 Supersedes date:

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.

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 (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: May cause respiratory irritation.

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:

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.



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

Derivatization reagent (RA19008R Kit)

Date of issue: 16.1.2018 Supersedes date:

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 4 Irritant - skin irritation and eye damage

HP 5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

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 Quantites 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.



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

Derivatization reagent (RA19008R Kit)

Date of issue: 16.1.2018 Supersedes date:

SECTION 16 OTHER INFORMATION

Date of issue: 16.1.2018

Revision notes:

Full text of H-phrases:

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.



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 (RA19008R Kit)

Date of issue: 16.1.2018 Supersedes date:

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

1.1 Product identifier

Trade name: Substrate Solution (RA19008R 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.



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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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.



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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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 glo

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



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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 can not 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:

Odour:

Odourless

Odour threshold:

PH-value:

Melting point/freezing point:

Initial boiling point and boiling range:

Light yellow

Odourless

Not determined.

Undetermined.

1461°C

Flash point:

Flammability (solid, gas):

Not applicable.

Not determined.

Decomposition temperature: Not determined. 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:

Organic solvents: 0.0% 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.



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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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 (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.



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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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 Quantites exemption, per IATA 2.6.10. Therefore, packaging does not have to be labeled as Dangerous Goods/Excepted Quantity



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 (RA19008R Kit)

Date of issue: 16.1.2018 Supersedes date:

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: 16.1.2018

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.



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

Derivatization buffer (RA19008R Kit)

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

1.1 Product identifier

Trade name: Derivatization buffer (RA19008R Kit)

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

Assay component – Histamine derivatization 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:

The product is not classified according to the CLP regulation.

2.2 Label elements

Hazard pictogram:

Void

Signal word:

Void

Hazard statements:

Void

Additional information:

EUH210 Safety data sheet available on request.

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.

 boric acid
 2.5-<5.5</td>
 233-139-2
 10043-35-3

Classification according to regulation 1272/2008/EC:

Repr. 1B, H360FD

For full text of H-phrases see section 16.



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

Derivatization buffer (RA19008R Kit)

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SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

General information:

No special measures required.

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

No special measures required.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Not required.

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).

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



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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7.3 Specific end use(s)

No further relevant information available.

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

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

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

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

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

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:

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

Respiratory protection: Not required.

Protection of hands: The glove material has to be impermeable and resistant to the

product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. 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 can not 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: Goggles recommended during refilling.

SECTION 9 Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Form: Fluid

Colour: According to product specification

Odour: Characteristic.
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 at 20°C: 23 hPa

Density: Not determined. Relative density: Not determined.



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Vapour density: Not determined. Evaporation rate: Not determined.

Solubility in / Miscibility with

water: Fully miscible.

Partition coefficient:

n-octanol/water: Not determined.

Viscosity:

Dynamic: Not determined. Kinematic: Not determined.

Solvent content:

Organic solvents: 0.0% Solids content: 97.0%

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: 10043-35-3, boric acid

Oral LD50 2660 mg/kg (rat)

Primary irritant effect:

Skin corrosion/irritation: Based on available data, the classification criteria are

not met.

Serious eye damage/irritation: Causes serious eye damage.

Respiratory or skin sensitisation: Based on available data, the classification criteria are

not met.

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction):

Germ cell mutagenicity: Based on available data, the classification criteria are

not met.



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

Derivatization buffer (RA19008R Kit)

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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: 10043-35-3, boric acid

LC50, 96h >1021 mg/l (Lepomis macrochirus).

279 mg/l (Ptychocheilus lucius)

EC50, 48h 133 mg/l (Daphnia magna) LC50, 21d 53.2 mg/l (Daphnia magna)

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:

Generally 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:

Smaller quantities can be disposed of with household waste.

European waste catalogue

HP 10 Toxic for reproduction

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



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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.

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 The product contains CAS: 10043-35-3, boric acid - substance of very high concern (SVHC) according to REACH, Article 57.

15.2 Chemical safety assessment

Chemical safety assessment has not been carried out.

SECTION 16 OTHER INFORMATION

Date of issue: 16.1.2018

Revision notes:

Full text of H-phrases:

H360FD May damage fertility. May damage the unborn child.

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.