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Information about Compilation of Safety Data Sheets

Product: SureLINK™ HRP Conjugation Kit

Company: SeraCare Life Sciences

Article numbers: 5610-0022, 5610-0023, 5610-0024

All components of the aforementioned kit had been classified according to Regulation (EC) No. 1907/2006 (REACH) and to Regulation (EC) No. 1272/2008 (GHS/CLP).

For the kit component Reducing Reagent (NaCNBH₃, article number 84-03-01), a Safety Data Sheet had been compiled (enclosure).

For the remaining kit components SureLINK™ Activated HRP (article numbers: 84-01-01, 84-01-02), HRP Storage Buffer (article number 84-04-01), and HRP Conjugation Buffer (article number 84-02-01), no Safety Data Sheets are required after classifications according to the Regulation (EC) No. 1907/2006 (REACH) and the Regulation (EC) No. 1272/2008 (GHS/CLP).

When handling the kit components, the general and specific safety precautions for laboratories and the corresponding directives have to be followed.

Date of issue: January 2018

medac

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Attachment

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Safety data sheet according to 1907/2006/EC, Article 31

Printing date 10.01.2018 Version number 2 Revision: 10.01.2018

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

1.1 Product identifier

Trade name: Reducing Reagent (NaCNBH₃)

Article number: 84-03-01 Registration number

This product is a mixture (see chapter 3). Registration number(s) is/are not available for this substance/these substances as the substance(s) or its/their use are exempted from registration according to Article 2 REACH Regulation (EC) No. 1907/2006, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.

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

Relevant identified uses: For Research Use. Uses advised against: For in vitro diagnosis.

Sector of Use SU24 Scientific research and development

Product category PC21 Laboratory chemicals

Process category PROC15 Use as laboratory reagent

1.3 Details of the supplier of the safety data sheet

Manufacturer/Distributor:

Manufacturer:

SeraCare Life Sciences (KPL)

910 Clopper Road

Gaithersburgh, Maryland 20878, USA

Distributor: medac GmbH Theaterstrasse 6 22880 Wedel, Germany

Informing department:

Product Safety

productsafety@medac.de

1.4 Emergency telephone number:

Giftinformationszentrum-Nord, Phone: ++49 551 19 240 (service in German and English, 24 hours permanently accessible).

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Acute Tox. 2 H300 Fatal if swallowed.

Acute Tox. 2 H310 Fatal in contact with skin.

Acute Tox. 2 H330 Fatal if inhaled.

Skin Corr. 1A H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage. Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms







GHS05 GHS06 GHS09

Signal word Danger

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Hazard-determining components of labelling:

sodium cyanotrihydroborate

sodium hydroxide

Hazard statements

H300+H310+H330 Fatal if swallowed, in contact with skin or if inhaled. H314 Causes severe skin burns and eye damage. Very toxic to aquatic life with long lasting effects. H410

Precautionary statements

Wear protective gloves / protective clothing / eye 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.

IF exposed or concerned: P310 Immediately call a POISON CENTER/doctor.

P405 Store locked up.

Additional information:

Labelling information:

Due to its small quantity the product is not subject to the labelling and packaging requirements of Art. 17 (please refer to Annex I, Number 1.5.2, Regulation (EC) No 1272/2008 (CLP)).

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII. vPvB: Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

SECTION 3: Composition/information on ingredients

3.1. Chemical characterisation: substances Not applicable. Product is a mixture.

3.2 Chemical characterisation: Mixtures

Description: Mixture of the substances listed below plus nonhazardous additions.

Dangerous components:		
CAS: 25895-60-7 EINECS: 247-317-2	sodium cyanotrihydroborate Flam. Sol. 1, H228; Water-react. 2, H261 Acute Tox. 2, H300; Acute Tox. 2, H310; Acute Tox. 2, H330 Eye Dam. 1, H318 Aquatic Acute 1, H400; Aquatic Chronic 1, H410	32%
CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-	sodium hydroxide Skin Corr. 1A, H314 O Acute Tox. 4, H302	5%

Additional information For the wording of the listed H-phrases please refer to Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information First aider: Take care of self-protection.

After inhalation

Supply fresh air.

Call a doctor immediately.

After skin contact

Instantly remove contaminated clothes.

Instantly wash with cupious amounts of water.

Call a doctor immediately.

After eve contact

Rinse eyes cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue

Instantly consult ophthalmologist.

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After swallowing

Let rinse out mouth and then drink plenty of water.

Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available for this mixture.

Information for doctor

Show Safety Data Sheet.

Treatment according to symptoms.

Danger No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents Product itself does not burn. Use fire fighting measures that suit the environment. For safety reasons unsuitable extinguishing agents For this mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

In the event of fire development of dangerous fumes or vapours possible.

Carbon monoxide (CO)

Carbon dioxide (CO₂)

Nitrogen oxides (NOx)

5.3 Advice for firefighters

Protective equipment:

In case of burning of a larger amount:

Stay in the danger area only with self-contained breathing apparatus.

Prevent skin and eye contact by keeping a safe distance or by wearing suitable protective clothing.

Additional information

Collect contaminated fire fighting water separately. It must not enter drains.

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:

Avoid reagent contact with eyes and skin.

Provide sufficient ventilation.

Advice for emergency responders: Protective equipment: see Section 8.

6.2 Environmental precautions:

Avoid release to the environment.

Do not empty into drains.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Afterwards clean with water and cleansing agent.

Dispose of the material collected according to respective national regulations.

Ensure adequate ventilation.

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 information on disposal.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Open and handle container with care.

Prevent inhalation, swallowing and contact with eyes and skin.

Information about protection against explosions and fires: No danger of explosion.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and containers:

Store container tightly closed in cool location.

Store at +2 °C to +8 °C.

Information about storage in one common storage facility: Because of the small quantities not required.

Further information about storage conditions:

Store in a locked cabinet with access restricted to technical experts or their assistants.

Storage class Void.

7.3 Specific end use(s) Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

Additional information about design of technical systems: No further data; see Section 7.

8.1 Control parameters

Components with critical values that require monitoring at the workplace:

DNELs No further relevant information available.

PNECs No further relevant information available.

CAS No. Designation of material % Type Value Unit

Additional Occupational Exposure Limit Values for possible hazards during processing: Not applicable.

Additional information: The official lists that were valid during the compilation were used as basis.

8.2 Exposure controls

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See Section 7.

Personal protective equipment

General protective and hygienic measures

The usual precautionary measures should be adhered to in handling the chemicals.

Avoid contact with eyes, skin and garments.

Remove contaminated clothing immediately.

Do not eat or drink while working.

Keep away from food and beverages.

Wash hands during breaks and at the end of the work.

Breathing equipment: No special precautions are necessary if handled correctly.

Protection of hands:

Protective gloves (AQL 1.5).

The breakthrough times stated below base on laboratory test methods which cannot fully simulate working conditions. It is the responsibility of the enduser to choose the appropriate gloves for his application. If working with substances or mixtures harmful in contact with skin, check the gloves beforehand for holes and fissures.

Material of gloves

Nitrile rubber, NBR

Thickness 0.11 mm.

Product quality must comply with standard EN 374.

Penetration time of glove material Penetration time > 240 min.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

Product has not been designed for permanent contact.

For the permanent contact gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

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For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

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

Nitrile rubber, NBR Thickness: 0.11 mm.

Product quality must comply with standard EN 374. Eye protection: Safety glasses (standard EN 166).

Body protection: Protective work clothing.

Limitation and supervision of exposure into the environment

Leakage into the environment must be prevented.

Do not empty into drains.

Risk management measures Void.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form: liquid Colour: colourless

Smell: No information available. Not determined.

Odour threshold:

Important information on protection of health and

environment, and on safety. No further relevant information available.

pH-value: Alkaline

Change in condition

Melting point/freezing point: No information available.

Initial boiling point and boiling range: For this concentration no information available.

Flash point: No informarion available. Inflammability (solid, gaseous) Mixture is not inflammable. **Decomposition temperature:** No information available. Self-inflammability: Not self-inflammable. Not explosive.

Explosive properties:

Critical values for explosion:

Lower: Not applicable. **Upper:** Not applicable. Oxidising properties Not oxidizing.

Steam pressure: No information available. Density No information available. Relative density No information available. Vapour density No information available. **Evaporation rate** No information available.

Solubility in / Miscibility with

Partition coefficient: n-octanol/water: No information available.

Viscosity:

dvnamic: No information available. kinematic: No information available.

Solvent content:

Organic solvents: 0,0 % Water: > 60 % Solids content: 37.0 %

9.2 Other information No further relevant information available.



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SECTION 10: Stability and reactivity

10.1 Reactivity For this mixture no relevant information available.

10.2 Chemical stability The product is chemically stable under the indicated storage conditions.

Thernak decomposition / conditions to be avoided: No decomposition if used and stored according to specifications.

10.3 Possibility of hazardous reactions

Dangerous reactions are not to be expected handling product according to its intended use.

10.4 Conditions to avoid: Warming.

10.5 Incompatible materials: For these concentrations no further relevant information available.

10.6 Hazardous decomposition products: In case of burning of larger amounts: See Section 5.

Additional information: No further relevant information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Fatal if swallowed, in contact with skin or if inhaled.

LD/LC50 values that are relevant for classification:

1310-73-2 sodium hydroxide

Oral LD50 2000 mg/kg (rat)

Specific symptoms in biological assay: No further relevant information available.

Primary irritant effect:

Skin corrosion/irritation

Causes severe skin burns and eye damage.

Serious eye damage/irritation

Causes serious eye damage.

after swallowing: Mucosal irritations in mouth, pharynx and oesophagus possible.

after inhalation: Irritations possible.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met. Other information (about experimental toxicology): No further relevant information available.

Subacute to chronic toxicity: No further relevant information available.

Additional toxicological information: No further relevant information available.

Toxicokinetics, metabolism and distribution No relevant information available.

Acute effects (acute toxicity, irritation and corrosivity) No acute toxicity information available for this product.

Sensitisation No sensitising effect known.

Repeated dose toxicity No further relevant information available.

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: Toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability No further relevant information available.

Other information: No further relevant information available.

Behaviour in environmental systems:

Components: No relevant information available.

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12.3 Bioaccumulative potential No relevant information available.

12.4 Mobility in soil No relevant information available.

Ecotoxical effects:

Remark: No further relevant information available.

Additional ecological information:

General notes:

Void.

Avoid transfer into the environment.

12.5 Results of PBT and vPvB assessment

PBT: PBT assessment not available as chemical safety assessment not required/not conducted. vPvB: vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects No relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product residues have to disposed of according to the Waste Framework Directive as well as national and regional regulations in each the latest versions.

Uncleaned packagings:

Recommendation: Uncleaned packagings have to be disposed of in the same manner as the product residues.

4.1 UN-Number	
ADR, IMDG, IATA	UN2922
4.2 UN proper shipping name	
ADR	2922 CORROSIVE LIQUID, TOXIC, N.O.S. (SODIUM HYDROXIDE, sodium cyanotrihydroborate), ENVIRONMENTALLY HAZARDOUS
MDG	CORROSIVE LIQUID, TOXIC, N.O.S. (SODIUM HYDROXIDE, sodium cyanotrihydroborate), MARINE POLLUTANT
ATA	CORROSIVE LIQUID, TOXIC, N.O.S. (SODIUM HYDROXIDE, sodium cyanotrihydroborate)



Class 8 (C5) Corrosive substances. Label 8 + 6.1

IMDG



Class 8 Corrosive substances.

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Label	8/6.1
IATA LEGAL CONTROL OF THE PROPERTY OF THE PRO	
Class Label	8 Corrosive substances. 8 (6.1)
14.4 Packing group ADR, IMDG, IATA	II
14.5 Environmental hazards: Marine pollutant: Special marking (ADR):	Symbol (fish and tree) Symbol (fish and tree)
14.6 Special precautions for user Kemler Number: EMS Number: Stowage Category Stowage Code	Warning: Corrosive substances. 89 F-A,S-B B SW2 Clear of living quarters.
14.7 Transport in bulk according to Annex II and the IBC Code	of Marpol Not applicable.
Transport/Additional information:	The transport regulations are cited according to international regulations and in the form applicable in Germany (GGVSE Possible national deviations in other countries are not considered. THESE TRANSPORT REGULATIONS APPLY TO THE WHOLE PACKAGE!
ADR Limited quantities (LQ) Excepted quantities (EQ) Transport category Tunnel restriction code	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml 2 E
IMDG Limited quantities (LQ) Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 2922 CORROSIVE LIQUID, TOXIC, N.O.S. (SODIUM HYDROXIDE, SODIUM CYANOTRIHYDROBORATE), 8 (6.1), II, ENVIRONMENTALLY HAZARDOUS

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Labelling according to Regulation (EC) No 1272/2008 See Section 2.

Directive 2012/18/EU

Named dangerous substances - ANNEX I Contains none of the listed substances.

Seveso category

H2 ACUTE TOXIC

E1 Hazardous to the Aquatic Environment

Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t

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REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 40

National regulations

Information about limitation of use:

Take note of the directive on the protection of young people at work in the latest version.

Take note of the directive on the safety and health at work for pregnant and breast feeding mothers and workers of childbearing age in the latest version.

Water hazard class: Void.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out.

SECTION 16: Other information

All information and recommodations are believed to be correct as of the date of this Safety Data Sheet but shall not be taken to be all inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. medac shall not be held liable for any damage resulting from handling or from contact with the above product.

Reasons for alteration

Classification, labelling and corresponding revision in accordance with Regulation (EC) No 1272/2008 (GHS/CLP).

Relevant phrases

H228 Flammable solid.

H261 In contact with water releases flammable gases.

H300 Fatal if swallowed.

H302 Harmful if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

H330 Fatal if inhaled.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de Replaces version from: 28.04.2014

Reason for alteration:

Classification, labeling in accordance with Regulation (EC) No 1272/2008 (GHS/CLP).

Change of manufacturer's address and of artice number(s).

General editorial revision.

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flam. Sol. 1: Flammable solids – Category 1

Water-react. 2: Substances and mixtures which in contact with water emit flammable gases - Category 2

Acute Tox. 2: Acute toxicity – Category 2 Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1A: Skin corrosion/irritation - Category 1A

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

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

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