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Information about Compilation of Safety Data Sheets

Product: HisDetector™ Nickel-HRP Conjugate
Company: SeraCare Life Sciences
Article number: 5820-0001

Both 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 HisDetector™ Nickel-HRP (article number 24-01-02), a Safety Data Sheet had been compiled (enclosure).

For the remaining kit component HisDetector™ Nickel-HRP Dilution Buffer (article number 24-02-00), no Safety Data Sheet is required after classification 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: February 2018

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Attachment

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

Printing date 12.02.2018 Version number 3 Revision: 12.02.2018

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

1.1 Product identifier

Trade name: HisDetector™ Nickel-HRP

Article number: 24-01-02
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:
RUO (Research Use Only).
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
Application of the substance / the mixture Immunochemical reagent for detection / auxiliary 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 phone: +49 4103 8006-0
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
According to Regulation (EC) No. 1272/2008 the mixture is classified as hazardous.
Carc. 1A H350i May cause cancer by inhalation. Route of exposure: Inhalation.
Repr. 1B H360D May damage the unborn child.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008
The product is classified and labeled in accordance with Regulation (EC) No 1272/2008 (GHS/CLP).

Hazard pictograms

GHS08

Signal word Danger

Hazard-determining components of labelling:
nickel sulfate hexahydrate

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Hazard statements
H350i May cause cancer by inhalation. Route of exposure: Inhalation.
H360D May damage the unborn child.

Precautionary statements
P201 Obtain special instructions before use.
P280 Wear protective gloves / protective clothing / eye protection
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.

Additional information:
Restricted to professional users.
Contains nickel sulfate hexahydrate. May produce an allergic reaction.
Labelling of packages where the contents do not exceed 125 ml
Hazard pictograms

GHS08

Signal word Danger

Hazard-determining components of labelling:
nickel sulfate hexahydrate
Hazard statements
Restricted to professional users.
H350i May cause cancer by inhalation. Route of exposure: Inhalation.
H360D May damage the unborn child.
Precautionary statements
P201 Obtain special instructions before use.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.

2.3 Other hazards Void.
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 characterisatiion: substances Not applicable. Product is a mixture.

3.2 Chemical characterisation: Mixtures
Description: Mixture of inorganic and organic compounds.

Dangerous components:		
CAS: 56-81-5 EINECS: 200-289-5 RTECS: MA 8050000	glycerol substance with a Community workplace exposure limit	25 - <40%
CAS: 10101-97-0 EINECS: 232-104-9 Index number: 028-009-00-5	nickel sulfate hexahydrate Resp. Sens. 1, H334; Muta. 2, H341; Carc. 1A, H350i; Repr. 1B, H360D; STOT RE 1, H372 Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Skin Sens. 1, H317	0.3 - <0.4%

SVHC Not applicable.
Additional information For the wording of the listed H-phrases please refer to Section 16.

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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.
Consult physician.
After skin contact
Remove contaminated clothes.
Instantly wash with cupious amounts of water.
In case of symptoms call a physician.
After eye contact
Rinse eyes cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
If necessary consult ophthalmologist.
After swallowing
Let rinse out mouth and then drink plenty of water.
In case of symptoms call a physician.

4.2 Most important symptoms and effects, both acute and delayed Allergic reactions
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 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
Can be released in case of fire:
Carbon monoxide (CO)
Carbon dioxide (CO_2)
Sulfur oxides

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: 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).

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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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Observe label precautions.
Open and handle container with care.
Information about protection against explosions and fires: No special measures required if handled correctly.

7.2 Conditions for safe storage, including any incompatibilities
Storage
Requirements to be met by storerooms and containers:
Store at -20 °C.
Store dry.
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 or with access restricted to technical experts or their assistants.
The indications are valid for the whole package.
Storage class Please see the respective national guidelines.

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:	
56-81-5 glycerol	
WEL	Long-term value: 10 mg/m³

DNELs No further relevant information available.
PNECs No further relevant information available.
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 the eyes and skin.
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.

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Material of gloves
Nitrile rubber, NBR
Natural rubber, NR
Thickness 0.11 mm.
Product quality must comply with standard EN 374.
Penetration time of glove material Penetration time > 480 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.
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
Natural rubber, NR
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 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 or pale yellow.
Smell:	No information available.
Odour threshold:	No information available.
Important information on protection of health and environment, and on safety.	No further relevant information available.
pH-value:	No information available.
Change in condition	
Melting point/freezing point:	No information available.
Initial boiling point and boiling range:	Ca. 100 °C
Flash point:	No informarion available.
Inflammability (solid, gaseous)	No information available.
Ignition temperature:	No information available.
Decomposition temperature:	No information available.
Self-inflammability:	Not self-inflammable.
Explosive properties:	Not explosive.
Critical values for explosion:	
Lower:	Not applicable.
Upper:	Not applicable.
Oxidising properties	No information available.
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	
Water:	Fully miscible.
Partition coefficient: n-octanol/water:	No information available.

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Viscosity:	
dynamic:	No information available.
kinematic:	No information available.
Solvent content:	
Organic solvents:	<40.0 %
Water:	~ 54 %
Solids content:	~ 5.8 %
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 The product is chemically stable under the indicated storage conditions.
Thernak decomposition / conditions to be avoided: No decomposition if used 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:
Strong oxidising agents
Strong bases.

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 Based on available data, the classification criteria are not met.

LD/LC50 values that are relevant for classification:		
56-81-5 glycerol		
Oral	LD_{50}	12,600 mg/kg (Rat)
10101-97-0 nickel sulfate hexahydrate		
Oral	LD_{50}	361 mg/kg (rat) (OECD Test Guideline 425)
Inhalative	LC_{50}/4 h	2.48 mg/l (rat) (OECD Test Guideline 403)

Specific symptoms in biological assay: No further relevant information available.
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.
after swallowing: Slight mucosal irritations in mouth, pharynx and oesophagus possible.
after inhalation: Slight 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 May cause allergic reactions.
Repeated dose toxicity May cause damage to organs through prolonged or repeated exposure.
CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
Germ cell mutagenicity Based on available data, the classification criteria are not met.
Carcinogenicity
May cause cancer by inhalation. Route of exposure: Inhalation.

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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:		
10101-97-0 nickel sulfate hexahydrate		
Oral	EC50/48 h	1 mg/l (Daphnia magna) (OECD Test Guideline 202)
	LC50/96 h	1.28 mg/l (fish)

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.

12.3 Bioaccumulative potential No relevant information available.

12.4 Mobility in soil No relevant information available.
Ecotoxical effects:
Remark: Toxic to fish and other aquatic organisms.
Additional ecological information:
General notes:
Do not let enter drains.
Water hazard class 2 (Self-assessment): hazardous for water.

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.

SECTION 14: Transport information

14.1 UN-Number	
ADR, ADN, IMDG, IATA	-
14.2 UN proper shipping name	
ADR, ADN, IMDG, IATA	-
14.3 Transport hazard class(es)	
ADR, ADN, IMDG, IATA	
Class	-
14.4 Packing group	
ADR, IMDG, IATA	-

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14.5 Environmental hazards: **Marine pollutant:**	No
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
Transport/Additional information:	Not classified as dangerous in the meaning of transport regulations as issued in the latest version. 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.
UN "Model Regulation":	-

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.
REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 27

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: Water hazard class 2 (Self-assessment): hazardous for water.

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.

Relevant phrases
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H332 Harmful if inhaled.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H341 Suspected of causing genetic defects.
H350i May cause cancer by inhalation. Route of exposure: Inhalation.
H360D May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
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: 09.10.2015
Reason for alteration:
Update of the classification.
Change of manufacturer's address and of artice number(s).

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Change of contact address.
General editorial revision.

Abbreviations and acronyms:
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord 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
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Resp. Sens. 1: Respiratory sensitisation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Muta. 2: Germ cell mutagenicity – Category 2
Carc. 1A: Carcinogenicity – Category 1Ai
Repr. 1B: Reproductive toxicity – Category 1B
STOT RE 1: Specific target organ toxicity (repeated exposure) – 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