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

Version number 2 Revision: 22.09.2017 Printing date 22.09.2017

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

1.1 Product identifier

Trade name: ABTS 1-Component Microwell Peroxidase Substrate Kit

Article number: 50-66-00, 50-66-06, 50-66-18

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 non-hazardous.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Product is not subject to labelling according to Regulation (EC) No. 1272/2008 (GHS/CLP).

Additional information:

Safety data sheet available on request.

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 characterisation: substances Not applicable. Product is a mixture.

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Eye Irrit. 2, H319

<1.0%

3.2 Chemical characterisation: Mixtures

Description: Water based solution

Dangerous components:

CAS: 77-92-9 citric acid

EINECS: 201-069-1 RTECS: GE 7350000 **SVHC** Not applicable.

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.

Seek medical treatment in case of complaints.

After skin contact

Remove contaminated clothes.

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.

In case of onset of symptoms consult doctor.

After swallowing

Let rinse out mouth and then drink plenty of water.

In case of disorders consult doctor.

4.2 Most important symptoms and effects, both acute and delayed No further televant information available.

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 No further relevant information available.

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:

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Avoid contact with skin and eyes.

Provide sufficient ventilation.

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).

Afterwards clean with water and cleansing agent.

Dispose of contaminated material as waste according to Section 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 information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling No special precautions necessary if handled correctly. **Information about protection against explosions and fires:** No special measures required.

7.2 Conditions for safe storage, including any incompatibilities No further relevant information available.

Storage

Requirements to be met by storerooms and containers: Store at +2 °C to +8 °C.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: The indications are valid for the whole package.

Storage class

Storage class 12 according to the German "Technical Rules for Hazardous Substances (TRGS) 510": Noncombustible liquids.

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: Not applicable.

DNELs Not applicable.

PNECs Not applicable.

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 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: Not required.

Protection of hands: Disposable medical gloves (AQL 1.5).

Material of gloves

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

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The product quality has to comply with DIN EN 455.

Penetration time of glove material Not applicable.

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.

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

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: 100 °C

Flash point:
Inflammability (solid, gaseous)
Ignition temperature:

Not applicable.
Not 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 Not applicable.

Steam pressure:No information available.DensityNo information available.Relative densityNo information available.Vapour densityNo information available.Evaporation rateNo information available.

Solubility in / Miscibility with

Water: Fully miscible.

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

Viscosity:

dynamic:kinematic:
No information available.
No information available.

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| 0,0 % |
|--------|
| 90,0 % |
| 0,1 % |
| |

9.2 Other informationNo further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability Product is under normal ambient conditions (room temperature) chemically stable.

Thernak 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: For these concentrations no further relevant information available.

10.6 Hazardous decomposition products:

For this/these concentartion/s no dangerous products of decomposition known.

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: Quantitative data about toxicity of this product are not available.

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

Primary irritant effect:

Skin corrosion/irritation In this concentration no irritant effects known.

Serious eye damage/irritation In this concentration no irritant effects known.

after swallowing: In this concentration no irritant effects known.

after inhalation: In this concentrations no irritant effects known.

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) No relevant information available.

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.

Other information: No further relevant information available.

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Behaviour in environmental systems:

Components: Accumulation in organisms is not to be expected.

12.3 Bioaccumulative potential Bioaccumulation is not to be expected.

12.4 Mobility in soil Mobility in soil due to the liquid status.

Additional ecological information:

General notes:

At present there are no ecotoxicological assessments.

Void.

12.5 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.

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.

| • | |
|---|---|
| 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 | - |
| 14.5 Environmental hazards: Marine pollutant: | No |
| 14.6 Special precautions for user | Not applicable. |
| 14.7 Transport in bulk according to Annex II o and the IBC Code | f Marpol 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 internation regulations and in the form applicable in Germany (GGVS Possible national deviations in other countries are not considered. THESE TRANSPORT REGULATIONS APPLY TO THE WHOLE PACKAGE! |
| UN "Model Regulation": | _ |

GB



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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.

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.

Other regulations, limitations and prohibitive regulations Void.

Substances of very high concern (SVHC) according to REACH, Article 57 Not applicable.

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.

This Safety Data Sheet is valid for the kit component ABTS Substrate Solution (article number 50-64-00) of the Protein Detector HRP Microwell Kit Anti-Human (article number 54-62-10).

A further Safety Data Sheet had been compiled for the kit component Peroxidase Stop Solution Concentrate (article number 50-85-00).

For the remaining kit components Coating Buffer Concentrate (article number 50-84-01), BSA Diluent/Blocking Solution Concentrate (article number 50-61-01), Wash Solution Concentrate (article number 50-63-01), 50% Glycerol (article number 50-83-00), Peroxidase Solution B (article number 50-65-00) and the Peroxidase-Labeled Antibody HPR Anti-Human IgG [H+L] (article number 04-10-06) 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).

Relevant phrases

H319 Causes serious eye irritation.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de Replaces version from: 18.07.2014

Reason for alteration:

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

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

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