

Gesellschaft für klinische Spezialpräparate mbH

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Information about Compilation of Safety Data Sheets

Product: 4CN 2-Component Membrane Peroxidase Substrate Kit

Company: SeraCare Life Sciences Article numbers: 5420-0020, 5420-0024

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 4 CN Solution (article numbers 50-73-01, 50-73-02), a Safety Data Sheet had been compiled (enclosure).

For the other kit component Peroxidase Substrate Solution B (article numbers 50-65-00, 50-65-02), 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: November 2017

medac

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Attachment

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Page 1/9

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

Version number 2 Printing date 02.11.2017 Revision: 02.11.2017

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

1.1 Product identifier

Trade name: 4 CN Solution

Article number: 50-73-01, 50-73-02

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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

STOT SE 1 H370 Causes damage to the eyes. Route of exposure: Oral, Inhalation, Dermal.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms





GHS02 GHS08

Signal word Danger

Hazard-determining components of labelling:

Methanol

Hazard statements

H225 Highly flammable liquid and vapour.

H370 Causes damage to the eyes. Route of exposure: Oral, Inhalation, Dermal.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P260 Do not breathe spray.

P280 Wear protective gloves / protective clothing / eye protection

P308 IF exposed or concerned:

(Contd. on page 2)



Printing date 02.11.2017 Version number 2 Revision: 02.11.2017

Trade name: 4 CN Solution

(Contd. of page 1)

P310 Immediately call a POISON CENTER/doctor.

P405 Store locked up.

Additional information:

Contains isocyanates. May produce an allergic reaction.

Labelling of packages where the contents do not exceed 125 ml

Hazard pictograms





GHS02 GHS08

Signal word Danger

Hazard-determining components of labelling:

Methanol

Hazard statements

H370 Causes damage to the eyes. Route of exposure: Oral, Inhalation, Dermal.

Precautionary statements

P308+P311 IF exposed or concerned: Call a POISON CENTER/doctor.

P405 Store locked up.

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 characterisatiion: substances Not applicable. Product is a mixture.

3.2 Chemical characterisation: Mixtures

Description: Water based solution

2000 Piloti Water Based Solution					
Dangerous components:					
CAS: 67-56-1 EINECS: 200-659-6 Index number: 603-001-00-X RTECS: PC 1400000	Methanol ◆ Flam. Liq. 2, H225 ◆ Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331 ◆ STOT SE 1, H370	10-20%			
CAS: 56-81-5 EINECS: 200-289-5 RTECS: MA 8050000	glycerol substance with a Community workplace exposure limit	10-20%			
CAS: 57-55-6 EINECS: 200-338-0 RTECS: TY 2000000	Methyl glycol substance with a Community workplace exposure limit	10-20%			
SVHC Not applicable.					

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 doctor in case of symptoms.

After skin contact

Remove contaminated clothes.

Instantly wash with cupious amounts of water.

Call a doctor immediately.

After eye contact

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

Consult ophthalmologist.

(Contd. on page 3)



Printing date 02.11.2017 Version number 2 Revision: 02.11.2017

Trade name: 4 CN Solution

(Contd. of page 2)

After swallowing

Let rinse out mouth and then drink plenty of water.

Instantly call for doctor, point to methanol.

4.2 Most important symptoms and effects, both acute and delayed

Irritant effects.

Breathing difficulty

Nausea

Visual disorders.

Risk of serious eye damage.

Blindness

Drying-out effect resulting in rough and chapped skin.

Information for doctor

Show Safety Data Sheet.

Treatment according to symptoms.

Danger Danger of skin resorption.

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 CO₂, foam or extinguishing powder.

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

Combustible.

Vapours are heavier than air and may spread along floors.

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

Can be released in case of fire:

Carbon monoxide (CO)

Carbon dioxide (CO₂)

Nitrogen oxides (NOx)

Formaldehyde

5.3 Advice for firefighters

Protective equipment:

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:

Do not inhale vapours/aerosols.

Avoid reagent contact with eyes and skin.

Provide sufficient ventilation.

Advice für emergency responders:

Wear protective equipment (see chapter 8). Keep unprotected persons away.

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).

Dispose of the material collected according to respective national regulations.

Afterwards clean with water and cleansing agent.

Ensure adequate ventilation.

(Contd. on page 4)



Printing date 02.11.2017 Version number 2 Revision: 02.11.2017

Trade name: 4 CN Solution

(Contd. of page 3)

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 Open and handle container with care.

Information about protection against explosions and fires:

Keep away from open flames, hot surfaces and sources of ignition.

7.2 Conditions for safe storage, including any incompatibilities

When handling customary laboratory quantities please follow the corresponding laboratory guidelines.

Requirements to be met by storerooms and containers:

Store container tightly closed.

Store at +2 °C to +8 °C.

Information about storage in one common storage facility: 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:

67-56-1 Methanol

WEL Short-term value: 333 mg/m³, 250 ppm Long-term value: 266 mg/m³, 200 ppm

56-81-5 glycerol

WEL Long-term value: 10 mg/m³

57-55-6 Methyl glycol

WEL Long-term value: 474* 10** mg/m³, 150* ppm

*total vapour and particulates **particulates

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

Personal protective equipment

General protective and hygienic measures

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

Do not inhale aerosols.

Avoid contact with the eyes and skin.

Remove contaminated clothing immediately.

Keep away from food and beverages.

Do not eat or drink while working.

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

Use skin protection cream for preventive skin protection.

Breathing equipment: Essential if vapours/aerosols develop.

(Contd. on page 5)



Printing date 02.11.2017 Version number 2 Revision: 02.11.2017

Trade name: 4 CN Solution

(Contd. of page 4)

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 Natural rubber, NR

Thickness 0.11 mm. Product quality must comply with standard EN 374.

Penetration time of glove material Penetration time > 120 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.

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: viscous
Colour: Colourless
Smell: Alcohol-like

Odour threshold: No information available.

Important information on protection of health and

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

pH-value: 5,4 - 5,8

Change in condition

Melting point/freezing point:

Initial boiling point and boiling range:

No information available.

No information available.

Flash point: No information available.

> 30 °C

Inflammability (solid, gaseous)Not applicable.Ignition temperature:Not available.

Decomposition temperature:Self-inflammability:
No information available.
Not self-inflammable.

Explosive properties: No further relevant information available.

Critical values for explosion:

Lower: No relevant information available.
Upper: No relevant information available.

Oxidising propertiesNo information available.Steam pressure:No information available.DensityNo information available.Relative densityNo information available.

(Contd. on page 6)



Printing date 02.11.2017 Version number 2 Revision: 02.11.2017

Trade name: 4 CN Solution

(Contd. of page 5)

Vapour densityNo information available.Evaporation rateNo information available.

Solubility in / Miscibility with

Water: Miscible

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

Viscosity:

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

Solvent content:

Organic solvents: > 15 % Water: > 50 % Solids content: 0 %

9.2 Other informationNo further relevant information available.

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 according to specifications.

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid:

Heat, flames, sparks.

Avoid contact with incompatible materials.

10.5 Incompatible materials:

Strong oxidising agents

Reducing agents.

Strong acids.

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:					
67-56-1 M	67-56-1 Methanol				
Oral	LD50	5628 mg/kg (rat)			
Dermal	LD50	15800 mg/kg (rabbit)			
Inhalative	LC50/4 h	131.25 mg/l (rat)			
56-81-5 glycerol					
Oral	LD50	12,600 mg/kg (Rat)			

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

Primary irritant effect:

Skin corrosion/irritation

Irritations.

Slight irritations

Drying-out effect resulting in rough and chapped skin.

Serious eye damage/irritation Causes severe eye irritation.

after swallowing:

After resorption of large quantities: nausea, intoxication, fatigue, ataxia (disorders of the coordination of muscle movement), vision disorders, loss of conciousness, damage of the kidneys.

(Contd. on page 7)



Printing date 02.11.2017 Version number 2 Revision: 02.11.2017

Trade name: 4 CN Solution

(Contd. of page 6)

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:

Methanol my damage central nervous system, peripheral nervous system, optical nerve, liver, kidneys, heart and blood irreversibly.

Additional toxicological information: No further relevant information available.

Toxicokinetics, metabolism and distribution No relevant information available.

Acute effects (acute toxicity, irritation and corrosivity) No further relevant information available.

Sensitisation No sensitising effect known.

Repeated dose toxicity No further relevant information available.

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No indications of CMR effects (Merck Safety Data Sheet methanol issued 2017/06/13).

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

Causes damage to the eyes. Route of exposure: Oral, Inhalation, Dermal.

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 No information available.

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability Readily biodegradable (OECD Test Guideline 301D).

Other information: No further relevant information available.

12.3 Bioaccumulative potential Bioaccumulation is not to be expected.

12.4 Mobility in soil No data available.

Additional ecological information:

General notes: 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.

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-				Hallovu	-	Omalion

14.1 UN-Number
ADR, IMDG, IATA UN1230

14.2 UN proper shipping name

ADR 1230 METHANOL IMDG, IATA METHANOL

(Contd. on page 8)



Printing date 02.11.2017 Version number 2 Revision: 02.11.2017

Trade name: 4 CN Solution

(Contd. of page 7)

14.3 Transport hazard class(es)

ADR





Class 3 (FT1) Flammable liquids.

Label 3+6.1

IMDG, IATA





Class 3 Flammable liquids.

Label 3+6.1

14.4 Packing group ADR, IMDG, IATA

14.5 Environmental hazards:

Marine pollutant: No

14.6 Special precautions for user Warning: Flammable liquids.

Kemler Number:336EMS Number:F-E,S-D

14.7 Transport in bulk according to Annex II of Marpol

and the IBC Code Not applicable.

Transport/Additional information: The transport regulations are cited according to international

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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) 1L
Transport category 2
Tunnel restriction code D/E

UN "Model Regulation": UN1230, METHANOL, 3 (6.1), II

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

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.

Class	Share in %		
ı	19.0		
NK	38.0		

Water hazard class: Void.

(Contd. on page 9)



Printing date 02.11.2017 Version number 2 Revision: 02.11.2017

Trade name: 4 CN Solution

(Contd. of page 8)

Other regulations, limitations and prohibitive regulations 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.

Relevant phrases

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

H370 Causes damage to the eyes. Route of exposure: Oral, Inhalation, Dermal.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de Replaces version from: 09.10.2015

Reason for alteration:

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

SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids - Category 2

Acute Tox. 3: Acute toxicity - Category 3

STOT SE 1: Specific target organ toxicity (single exposure) - Category 1