

## Information about Compilation of Safety Data Sheets

**Product: *p*NPP Microwell Substrate System (Tablets and DEA Buffer)**  
**Company: SeraCare Life Sciences**  
**Article number: 5120-0056**

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 DEA Buffer Solution (article number 50-80-02) which is also available separately under the article number 5120-0058, a Safety Data Sheet had been compiled (enclosure).

For the other kit component Phosphatase Substrate *p*-Nitrophenyl Phosphate Hexahydrate Disodium Salt Tablets (*p*NPP Substrate Tablets, article number 50-80-01) which is as well also available separately under the article number 5120-0057, 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: January 2018

**medac**

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

Printing date 03.01.2018

Version number 2

Revision: 14.11.2017

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** DEA Buffer Solution**Article number:** 5120-0058, 50-80-02**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**Uses advised against** In-vitro diagnosis.**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

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**1.4 Emergency telephone number:**

GifTinformatiionszentrum-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**

Skin Irrit. 2 H315 Causes skin irritation.

Eye Dam. 1 H318 Causes serious eye damage.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

**2.2 Label elements****Labelling according to Regulation (EC) No 1272/2008**

The product is labelled according to Regulation (EC) No. 1272/2008 (GHS/CLP).

**Hazard pictograms**

GHS05 GHS08

**Signal word** Danger**Hazard-determining components of labelling:**

diethanolamine

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**Hazard statements**

H315 Causes skin irritation.

H318 Causes serious eye damage.

H373 May cause damage to organs through prolonged or repeated exposure.

**Precautionary statements**

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P315 Get immediate medical advice/attention.

P405 Store locked up.

**Labelling of packages where the contents do not exceed 125 ml**
**Hazard pictograms**


GHS05 GHS08

**Signal word** Danger

**Hazard-determining components of labelling:**

diethanolamine

**Hazard statements**

H318 Causes serious eye damage.

**Precautionary statements**

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P315 Get immediate medical advice/attention.

P405 Store locked up.

**2.3 Other hazards**
**Results of PBT and vPvB assessment**
**PBT:** PBT assessment not available as chemical safety assessment not required/not conducted.

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

### SECTION 3: Composition/information on ingredients

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

**3.2 Chemical characterisation: Mixtures**
**Description:** Water based solution

**Dangerous components:**

CAS: 111-42-2	diethanolamine	 STOT RE 2, H373  Eye Dam. 1, H318  Acute Tox. 4, H302; Skin Irrit. 2, H315	50-100%
EINECS: 203-868-0			
Index number: 603-071-00-1			
RTECS: KL 2975000			

**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; consult doctor in case of symptoms.

**After skin contact**

Remove contaminated clothes.

Instantly wash with water and soap and rinse thoroughly.

In case of symptoms call a physician.

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**After eye contact**

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

Call a doctor immediately.

**After swallowing**

Rinse out mouth.

Let drink water (2 glasses maximum).

Call doctor.

**4.2 Most important symptoms and effects, both acute and delayed** No further relevant 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**

In the event of surrounding fire development of hazardous vapours possible.

In the event of fire may develop:

Nitrous gases

Nitrogen oxides (NO<sub>x</sub>)

**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 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).

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.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Keep containers tightly sealed.

Open and handle container with care.

No special precautions necessary if handled correctly.

#### Information about protection against explosions and fires:

No special measures required.

The product is not flammable

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

#### Storage

**Requirements to be met by storerooms and containers:** Store container tightly closed.

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

**Further information about storage conditions:** Store refrigerated (2-8 °C).

**Storage class** 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:** Not applicable.

**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 the eyes and skin.

Do not inhale aerosols.

Instantly remove any soiled and impregnated garments.

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.

Breathing protection recommended.

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

##### Material of gloves

Natural rubber, NR

Nitrile rubber, NBR

Thickness 0.11 mm.

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.

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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

Natural rubber, NR

Thickness: 0.11 mm.

**Eye protection:** Tightly sealed safety glasses (DIN 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:** Ammonia-like

**Odour threshold:** Not determined.

**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:** 0 °C

**Initial boiling point and boiling range:** 100 °C

**Flash point:** Not applicable.

**Inflammability (solid, gaseous)** Not applicable.

**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.

**Steam pressure at 20 °C:** 23 hPa

**Density at 20 °C** 1 g/cm<sup>3</sup>

**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.

##### Viscosity:

**dynamic:** No information available.

**kinematic:** No information available.

##### Solvent content:

**Organic solvents:** 52,5 %

**Water:** 47,5 %

**Solids content:** 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.  
**Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

**10.3 Possibility of hazardous reactions** No further relevant information available.

**10.4 Conditions to avoid:** No further relevant information available.

**10.5 Incompatible materials:** No data 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** Based on available data, the classification criteria are not met.

#### LD/LC50 values that are relevant for classification:

##### 111-42-2 diethanolamine

Oral	LD50	1600 mg/kg (rat)
Dermal	LD50	12200 mg/kg (rabbit)

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

#### Primary irritant effect:

##### Skin corrosion/irritation

Causes skin irritation.

##### Serious eye damage/irritation

Causes serious eye damage.

**after swallowing:** Harmful if swallowed.

**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)

Strong irritations at skin and eyes with the danger of severe ocular damage.

**Sensitisation** No sensitising effect known.

**Repeated dose toxicity** No further relevant information available.

**CMR effects (carcinogenicity, 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

May cause damage to organs through prolonged or repeated exposure.

**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** Readily biodegradable (OECD Test Guideline 301D).

**Other information:** No further relevant information available.

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**Behaviour in environmental systems:**
**Components:** No relevant information available.

**12.3 Bioaccumulative potential** Bioaccumulation is not to be expected.

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

**Ecotoxicological effects:**
**Remark:** No further relevant information 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 be disposed of according to the Waste Framework Directive as well as national and regional regulations in each of 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 -

**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:**

 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!**
**UN "Model Regulation":**

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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.

**Hazard pictograms** See Section 2.

**Signal word** See Section 2.

**Hazard-determining components of labelling:** See Section 2.

**Hazard statements** See Section 2.

**Precautionary statements** 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 %
NK	52.5

**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 recommendations 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.

H318 Causes serious eye damage.

H373 May cause damage to organs through prolonged or repeated exposure.

**Department issuing data specification sheet:** Product Safety

**Contact:** productsafety@medac.de

**Replaces version from:** 14.05.2013

**Reason for alteration:** Change of manufacturer's address and of article number(s).

#### 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

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2