

Information about Compilation of Safety Data Sheets

Product: HistoMark® BLUE Phosphatase Substrate Kit
Company: SeraCare Life Sciences
Article number: 5510-0037

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 components PhThaloBLUE Solution (article number 71-00-03), Activator Solution (article number 71-00-01), and Contrast RED Solution (article number 71-00-05, also available separately under the article number 5540-0001), Safety Data Sheets had been compiled (enclosure).

For the remaining kit component Buffered Substrate Solution (Artikelnummer 71-00-04), 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: March 2018

medac

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

Printing date 27.03.2018

Version number 2

Revision: 27.03.2018

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** PhThaloBLUE Solution**Article number:** 71-00-03**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.

Labelling of packages where the contents do not exceed 125 ml 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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3.2 Chemical characterisation: Mixtures**Description:** Mixture of the substances listed below plus nonhazardous additions.**Dangerous components:**

| | | | |
|--|--------------------|--|------|
| CAS: 111-46-6 EINECS: 203-872-2 Index number: 603-140-00-6 RTECS: ID 5950000 | 2,2'-oxybisethanol | ⚠ Acute Tox. 4, H302 | 80% |
| CAS: 7647-01-0 EINECS: 231-595-7 Index number: 017-002-00-2 RTECS: MW 9620000 | hydrogen chloride | ⚠ Skin Corr. 1B, H314 ⚠ STOT SE 3, H335 | 3.3% |

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 copious 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 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 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** 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 (CO₂)Nitrogen oxides (NO_x)**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.

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Additional information

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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).
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

Keep containers tightly sealed.
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 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:

111-46-6 2,2'-oxybisethanol

WEL Long-term value: 101 mg/m³, 23 ppm

7647-01-0 hydrogen chloride

WEL Short-term value: 8 mg/m³, 5 ppm
Long-term value: 2 mg/m³, 1 ppm
(gas and aerosol mists)

DNELs Not applicable.

PNECs Not applicable.

Ingredients with biological limit values: Void.

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.

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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.

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: | clear, liquid |
| Colour: | pinkish-brown |
| 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: < 2.0

Change in condition

| | |
|---|--------|
| Melting point/freezing point: | < 0 °C |
| Initial boiling point and boiling range: | 100 °C |

| | |
|--|---------------------------|
| Flash point: | No information available. |
| Inflammability (solid, gaseous) | No information available. |
| Ignition temperature: | No information available. |
| Decomposition temperature: | No information available. |
| Self-inflammability: | Not self-inflammable. |

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| | |
|--|--|
| Explosive properties: | No further relevant information available. |
| Critical values for explosion: | |
| Lower: | No relevant information available. |
| Upper: | No relevant information available. |
| 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: | Miscible |
| Partition coefficient: n-octanol/water: | No information available. |
| Viscosity: | |
| dynamic: | No information available. |
| kinematic: | No information available. |
| Solvent content: | |
| Organic solvents: | 80.0 % |
| Water: | ca. 15.0 % |
| Solids content: | ca. 0.5 % |

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.

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

LD/LC50 values that are relevant for classification:

111-46-6 2,2'-oxybisethanol

| | | |
|--------|------------------|-----------------------|
| Oral | LD ₅₀ | 12,565 mg/kg (rat) |
| Dermal | LD ₅₀ | 11,890 mg/kg (rabbit) |

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.

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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 (carcinogenicity, 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:** No further relevant information available.**12.2 Persistence and degradability** Readily biodegradable (OECD Test Guideline 301D).**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.**Ecotoxicological effects:****Remark:** No further relevant information available.**Additional ecological information:****General notes:**

Void.

Do not let enter drains.

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 be 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

-

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**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:

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.**
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 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.

H314 Causes severe skin burns and eye damage.

H335 May cause respiratory irritation.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de

Replaces version from: 18.07.2014

Reason for alteration:

Update of the classification.

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

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

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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 Corr. 1B: Skin corrosion/irritation – Category 1B
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** Activator Solution**Article number:** 71-00-01**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:

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.

Labelling of packages where the contents do not exceed 125 ml 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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Trade name: Activator Solution

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

| | | | |
|----------------------------|----------------|---|----|
| CAS: 7632-00-0 | sodium nitrite |  Ox. Sol. 3, H272 | 2% |
| EINECS: 231-555-9 | |  Acute Tox. 3, H301 | |
| Index number: 007-010-00-4 | |  Aquatic Acute 1, H400 | |

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 copious 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 ophthalmologist.

After swallowing

Let rinse out mouth and then drink plenty of water.

In case of disorders consult doctor.

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:

Avoid reagent contact with eyes and skin.

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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).

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** 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 required according to German regulations.

DNELs Not applicable.**PNECs** Not applicable.**Ingredients with biological limit values:** Void.

| 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: | clear, slightly 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: | Ca. 0°C |
| Initial boiling point and boiling range: | 100 °C |

| | |
|--|---------------------------|
| Flash point: | Not applicable. |
| Inflammability (solid, gaseous) | Not applicable. |
| Ignition temperature: | 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 at 20 °C: | 23 hPa |
| Density | No information available. |
| Relative density | No information available. |
| Vapour density | No information available. |
| Evaporation rate | No 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. |

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| | |
|--------------------------|----------|
| Solvent content: | |
| Organic solvents: | 0.0 % |
| Water: | > 50.0 % |
| Solids content: | ca. 2 % |

| | |
|------------------------------|--|
| 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.**Thermal 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 concentration/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** Slight irritations possible.**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 (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** 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.

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12.2 Persistence and degradability

The methods for determining the biological degradability are not applicable to inorganic substances / mixtures of inorganic substances.

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.

Ecotoxicological effects:

Remark: No further relevant information available.

Additional ecological information:

General notes:

Void.

Do not let enter drains.

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 be 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 -

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.

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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.**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 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

H272 May intensify fire; oxidiser.

H301 Toxic if swallowed.

H400 Very toxic to aquatic life.

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 article number(s).

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)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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

Ox. Sol. 3: Oxidizing solids – Category 3

Acute Tox. 3: Acute toxicity – Category 3

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

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** Contrast RED Solution**Article number:** 71-00-05, 5540-0001**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**

Eye Dam. 1 H318 Causes serious eye damage.

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

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

aluminium sulfate hydrate

Hazard statements

H318 Causes serious eye damage.

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Precautionary statements

P280 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.

P310 Immediately call a doctor.

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

GHS05

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

aluminium sulfate hydrate

Hazard statements

H318 Causes serious eye damage.

Precautionary statements

P280 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.

P310 Immediately call a doctor.

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.**3.2 Chemical characterisation: Mixtures****Description:** Mixture of the substances listed below plus nonhazardous additions.**Dangerous components:**

| | | |
|--|--|-----|
| CAS: 56-81-5 EINECS: 200-289-5 RTECS: MA 8050000 | glycerol substance with a Community workplace exposure limit | 30% |
| CAS: 17927-65-0 EINECS: 233-135-0 | aluminium sulfate hydrate Met. Corr.1, H290; Eye Dam. 1, H318 | 5% |

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.

In case of symptoms call a physician.

After skin contact

Remove contaminated clothes.

Wash with copious 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.

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Instantly 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

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 may develop:

Carbon monoxide (CO)

Carbon dioxide (CO₂)

Nitrogen oxides (NO_x)

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).

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**

Open and handle container with care.

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Prevent contact with skin and eyes.

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 container tightly closed.

Store at +2 °C to +8 °C.

Information about storage in one common storage facility: For this mixture no further information available.**Further information about storage conditions:** The indications are valid for the whole package.**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:****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:**

Disposable medical 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.

The product quality has to comply with DIN EN 455.

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

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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: | reddish |
| Smell: | No information available. |
| Odour threshold: | No 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 information available.
Not applicable.

Inflammability (solid, gaseous) Not applicable.

Ignition temperature: 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: No information available.

Steam pressure: No information available.

Density: No information available.

Not determined.

Relative density: No information available.

Vapour density: No information available.

Evaporation rate: No 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: 30.0 %

Water: ca. 60 %

Solids content: 5.1 %

9.2 Other information No 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 and stored according to specifications.

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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:** 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 LD₅₀ 12,600 mg/kg (Rat)**17927-65-0 aluminium sulfate hydrate**Oral LD₅₀ >5,000 mg/kg (rat)**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**

Causes serious eye damage.

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** No sensitising effect known.**Repeated dose toxicity** No further relevant information available.**CMR effects (carcinogenicity, 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:** No further relevant information available.**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.**Ecotoxicological effects:****Remark:** No further relevant information available.

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Additional ecological information:**General notes:**

Void.

Do not let enter drains.

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 be 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

-

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

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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 | 30.0 |

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 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

H290 May be corrosive to metals.

H318 Causes serious eye damage.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de

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

Met. Corr. 1: Corrosive to metals – Category 1

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