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

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

1.1 Product identifier

Trade name: Contrast BLUE Solution

Article number: 71-00-06, 5540-0002

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 Informing department: Product Safety productsafety@medac.de

phone: +49 4103 8006-0

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



Signal word Danger

Hazard-determining components of labelling: aluminium sulfate hydrate

Hazard statements H318 Causes serious eye damage.

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(Contd. of page 1) Precautionary statements Wear protective gloves / protective clothing / eye protection P280 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor. P310 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** Wear protective gloves / protective clothing / eye protection P280 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.

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 |
|----------------|-------|-------|----------|
|----------------|-------|-------|----------|

Dangerous components: CAS: 56-81-5 glycerol 10% EINECS: 200-289-5 substance with a Community workplace exposure limit 10% CAS: 17927-65-0 aluminium sulfate hydrate 5% EINECS: 233-135-0 ♦ 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.

vPvB: Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

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 (NOx)

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-purple | |
| Smell: | No information available. | |
| Odour threshold: | No information available. | |
| pH-value: | No information available. | |
| Change in condition | | |
| Melting point/freezing point: | ca. 0 °C | |
| Initial boiling point and boiling range: ca. 100 °C | | |
| Flash point: | No information available. | |
| 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. | |
| 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: | 10.0 % | |
| Water: | ca. 80 % | |
| 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.

10.3 Possibility of hazardous reactions No dangerous reactions known.



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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:

Serious eye damage/irritation

Causes serious eye damage.

after swallowing: Slight mucosal irritations in mouth, pharynx and oesophagus possible.

Skin corrosion/irritation Based on available data, the classification criteria are not met.

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 (carcinogenity, 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. Ecotoxical effects: Remark: No further relevant information available. Additional ecological information:

General notes:

Void.



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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: | Not applicable. | |
| 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

National regulations

Information about limitation of use:

Take note of the directive on the protection of young people at work in the latest version.



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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 10.0

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 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

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

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