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

Printing date 30.07.2018 Version number 5 Revision: 30.07.2018

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

1.1 Product identifier

Trade name: MGG-QUICK Reagent C (dark-blue): Nuclear and cytoplasmic differential stain (buffered solution of thiazine stabilized with methanol)

Article number: MAD-106.500, MAD-106.1000, MAD-106.2500

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: For in vitro diagnosis. Uses advised against:

No further relevant information available.

Sector of Use SU20 Health services

Product category PC21 Laboratory chemicals

Process category PROC15 Use as laboratory reagent

Application of the substance / the mixture

Immunochemical reagent for detection / auxiliary reagent for in-vitro diagnosis.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Distributor:

Manufacturer:

Master Diagnóstica, S.L.

Avenida del Conocimiento, nº 100

P.T. Ciencias de la Salud

Granada 18016, Spain

Distributor:

medac GmbH

Theaterstrasse 6

22880 Wedel, Germany

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 The product is classified according to CLP regulation.

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.

phone: +49 4103 8006-0



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1- < 2.5%

SECTION 3: Composition/information on ingredients

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

3.2 Chemical characterisation: Mixtures Description: Aqueous-alcoholic solution.

Dangerous components:

CAS: 67-56-1 Methanol

Index number: 603-001-00-X Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331

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

Instantly remove contaminated clothes.

Instantly wash with water and soap and rinse thoroughly.

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.

Call for physician (point to methanol).

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

For these concentrations no further relevant information available.

5.3 Advice for firefighters

Protective equipment:

In case of fire of large quantities:

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/safety glasses.

Additional information

Collect contaminated fire fighting water separately. It must not enter drains.

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Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:

Do not inhale vapours/aerosols.

Avoid reagent contact with eyes and skin.

Provide sufficient ventilation.

Advice for emergency responders: protective equipment: see Section 8. Keep unprotected personnel 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 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 No special precautions necessary if handled correctly.

Information about protection against explosions and fires: No special measures required if handled correctly.

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 +15 °C to +25 °C.

Information about storage in one common storage facility: For this mixture no further information available.

Further information about storage conditions:

Protect from heat and direct sunlight.

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:

67-56-1 Methanol

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

Long-term value: 266 mg/m³, 200 ppm

Sk

DNELs For these concentrations no relevant information available.

PNECs For these concentrations no 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.

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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:

Protective gloves (AQL 1.5).

The breakthrough times stated below base on laboratory test methods which cannot fully simulate working conditions. It is the responsibility of the end user to choose the appropriate gloves for his application. If working with substances or mixtures harmful in contact with skin, check the gloves beforehand for holes and fissures.

Material of gloves

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

Product quality must comply with standard EN 374.

Penetration time of glove material

Not applicable.

Penetration time > 120 min.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

Product has not been designed for permanent contact.

For the permanent contact gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

As protection from splashes gloves made of the following materials are suitable:

Nitrile rubber, NBR Natural rubber, NR Thickness: 0.11 mm.

Eye protection: Safety glasses (standard EN 166).

Body protection: Protective work clothing.

Limitation and supervision of exposure into the environment Do not empty into drains.

Risk management measures Void.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form: liquid, opaque cobalt blue smell: unpleasant

Odour threshold: No information available.

pH-value at 20 °C:

Change in condition

Melting point/freezing point: ca. 0 °C Initial boiling point and boiling range: ca. 100 °C

Flash point: >60 °C
Inflammability (solid, gaseous) Not applicable.

Ignition temperature:No information available. **Decomposition temperature:**No information available.

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Self-inflammability: No information available.

Explosive properties: No further relevant information available.

Critical values for explosion:

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

Oxidising propertiesNot applicable.Steam pressure at 20 °C:24.8 hPaDensity at 20 °C1.034 g/cm³Relative density at 20 °C1.034 g/m³

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 at 20 °C: 1.86 cP

kinematic: No information available.

Solvent content:

 Organic solvents:
 1 - <2.5 %</td>

 Water:
 ≥95.0 %

 Solids content:
 <1 %</td>

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.

Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to the specifications.

10.3 Possibility of hazardous reactions

Dangerous reactions are not to be expected when handling the product according to its intended use.

10.4 Conditions to avoid:

Warming. Sunlight.

10.5 Incompatible materials: Oxidizing substances.

10.6 Hazardous decomposition products:

For this/these concentration/s no dangerous products of decomposition are 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:

67-56-1 Methanol

 $\begin{array}{c|cccc} Oral & LD_{50} & 5,630 \text{ mg/kg (rat)} \\ Dermal & LD_{50} & 15,800 \text{ mg/kg (rabbit)} \\ Inhalative & LC_{50}/4 \text{ h} & 131.25 \text{ mg/l (rat)} \\ \end{array}$

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.

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Serious eye damage/irritation Based on available data, the classification criteria are not met.

after swallowing: Harmful if swallowed.

after inhalation:

Harmful if inhaled.

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 Product is easily biodegradable.

Other information: No further relevant information available.

Behaviour in environmental systems:

Components: No relevant information available.

12.3 Bioaccumulative potential Does not significantly accumulate in organisms.

12.4 Mobility in soil No 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.

GB



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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 Marpand the IBC Code	ol Not applicable.
Transport/Additional information:	Not classified as dangerous in the meaning of transport regulations as issued in the latest version. The transport regulations are cited according to internation regulations and in the form applicable in Germany (GGVS Possible national deviations in other countries are not considered.
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 Methanol

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 40, 69

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 %
I	1- <2.5

Water hazard class: Void.

Other regulations, limitations and prohibitive regulations 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.



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Relevant phrases

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

H370 Causes damage to organs.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de Replaces version from: 20.11.2013

Reason for alteration: Update of the classification.

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

General editorial revision. Change of contact address.

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids - Category 2

Acute Tox. 3: Acute toxicity - Category 3

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