

Gesellschaft für klinische Spezialpräparate mbH

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Information about Compilation of Safety Data Sheets

Product: PermaBlue Plus/AP, Ready To Use 110 ml

Company: Diagnostic BioSystems, Inc.

Article number: K058-110

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 PermaBlue Plus/AP Substrate Buffer (Component 2, article number: K 058B) and PermaBlue Plus/AP Chromogen (Component 1, article number: K 058C), Safety Data Sheets had been compiled (enclosure).

When handling the kit components, the general and specific safety precautions for laboratories and the corresponding directives have to be followed.

Date of issue: August 2017

medac

Product Safety Safety Health Environment Phone: +49 (0)4103 8006 0 Fax: +49 (0)4103 8006 100

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Theaterstrasse 6 22880 Wedel Germany

Attachment

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

Printing date 21.08.2017 Version number 1 Revision: 21.08.2017

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

1.1 Product identifier

Trade name: Perma Blue™/AP, Perma Blue™/AP-AUTO, Perma Blue™ Plus/AP, Component 1

Article number: K058C Comp1

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

1.3 Details of the supplier of the safety data sheet

Manufacturer/Distributor:

Manufacturer:

Diagnostic BioSystems, Inc.

6616 Owens Drive

Pleasanton, CA 94588, USA

Distributor: medac GmbH Theaterstr. 6

22880 Wedel Germany Phone: +49 4103 8006-0

Informing department:

Product Safety

productsafety@medac.de

1.4 Emergency telephone number:

Giftinformationszentrum-Nord, Phone: ++49 551 19 240 (service in German and English, 24 hours permanently accessible).

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

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

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

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms





GHS02 GHS08

Signal word Danger

Hazard-determining components of labelling:

Methanol

Hazard statements

H225 Highly flammable liquid and vapour.

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Trade name: Perma Blue™/AP, Perma Blue™/AP-AUTO, Perma Blue™ Plus/AP, Component 1

(Contd. of page 1)

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

Precautionary statements

P202 Do not handle until all safety precautions have been read and understood.

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

P260 Do not breathe spray.

P280 Wear protective gloves / protective clothing / eye protection P308+P311 IF exposed or concerned: Call a POISON CENTER/doctor.

P405 Store locked up.

Additional information: Restricted to professional users.

Labelling of packages where the contents do not exceed 125 ml

Hazard pictograms





GHS02 GHS08

Signal word Danger

Hazard-determining components of labelling:

Methanol

Hazard statements

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

Precautionary statements

P202 Do not handle until all safety precautions have been read and understood.

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

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

P405 Store locked up.

2.3 Other hazards

Results of PBT and vPvB assessment

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

SECTION 3: Composition/information on ingredients

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

3.2 Chemical characterisation: Mixtures

Description: Water based solution

Dangerous components:

CAS: 67-56-1 Methanol EINECS: 200-659-6 Flam. Lic

EINECS: 200-659-6 Flam. Liq. 2, H225 Index number: 603-001-00-X Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331

Additional information For the wording of the listed H-phrases please refer to Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information First aider: Take care of self-protection.

After inhalation Supply fresh air; consult doctor in case of symptoms.

After skin contact

Remove contaminated clothes.

Instantly wash with cupious amounts of water.

Call in 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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25-50%



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Trade name: Perma Blue™/AP, Perma Blue™/AP-AUTO, Perma Blue™ Plus/AP, Component 1

(Contd. of page 2)

Instantly consult ophthalmologist.

After swallowing

Let rinse out mouth and then drink plenty of water.

Call a doctor immediately.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Information for doctor

Show Safety Data Sheet.

Treatment according to symptoms.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents CO₂, foam or extinguishing powder.

For safety reasons unsuitable extinguishing agents For this mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

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

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

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 aerosols.

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.

Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

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Trade name: Perma Blue™/AP, Perma Blue™/AP-AUTO, Perma Blue™ Plus/AP, Component 1

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

Requirements to be met by storerooms and containers:

Store container tightly closed.

Store at +2 °C to +8 °C.

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

Further information about storage conditions:

Store in a locked cabinet or with access restricted to technical experts or their assistants.

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 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.

Do not inhale aerosols.

Avoid contact with the eyes and skin.

Remove contaminated clothing immediately.

Do not eat or drink while working.

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

Breathing equipment:

Filter A (according to standard EN 3181) for vapours of organic compounds...

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Protection of hands:

Protective gloves (AQL 1.5).

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

Material of gloves

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

Product quality must comply with standard EN 374.

Penetration time of glove material Penetration time > 120 min.

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

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

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

Nitrile rubber, NBR Natural rubber, NR Thickness: 0.11 mm. Penetration time > 120 min.

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: Colourless
Smell: Alcoholoc.
Odour threshold: Not determined.

pH-value: No information available.

Change in condition

Melting point/freezing point: Ca. 0 °C

Flash point: < 23 °C Inflammability (solid, gaseous) Not applicable.

Ignition temperature: Not available.

Decomposition temperature: Self-inflammability:No information available.
No information available.

Explosive properties: Product is not explosive. However, formation of explosive air/steam mixtures is

possible.

Critical values for explosion:

Lower: No relevant information available.

Upper: No relevant information available.

Steam pressure: Not determined.

Density at 20 °C 0.88268 g/cm³

Relative density
Vapour density
No information available.
No information available.
No information available.
No information available.

Solubility in / Miscibility with

Water: Fully miscible.

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

Viscosity:

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

Solvent content:

 Organic solvents:
 50.0 %

 Water:
 50.0 %

 Solids content:
 0.0 %

9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.



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Trade name: Perma Blue™/AP, Perma Blue™/AP-AUTO, Perma Blue™ Plus/AP, Component 1

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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.

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:

67-56-1 Methanol

Oral	LD50	5630 mg/kg (rat)
		15800 mg/kg (rab)
Inhalative	LC50/4 h	131.25 mg/l (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 Based on available data, the classification criteria are not met.

after swallowing: Harmful if swallowed. **after inhalation:** Harmful if inhaled.

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

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

STOT-repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity

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 Mobility in soil due to the liquid status.

(Contd. on page 7)



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Trade name: Perma Blue™/AP, Perma Blue™/AP-AUTO, Perma Blue™ Plus/AP, Component 1

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Additional ecological information:

General notes: Void.

12.5 Results of PBT and vPvB assessment

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

12.6 Other adverse effects No relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product residues have to disposed of according to the Waste Framework Directive as well as national and regional regulations in each the latest versions.

Uncleaned packagings:

Recommendation: Disposal according to the respective national official regulations.

SECTION 14: Transport information	
14.1 UN-Number ADR, IMDG, IATA	UN1230
14.2 UN proper shipping name ADR IMDG, IATA	1230 METHANOL solution METHANOL solution
14.3 Transport hazard class(es)	
ADR	
Class Label	3 (FT1) Flammable liquids. 3+6.1
IMDG	
Class Label	3 Flammable liquids. 3/6.1
IATA	
Class Label	3 Flammable liquids. 3 (6.1)
14.4 Packing group ADR, IMDG, IATA	II
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user Kemler Number: EMS Number: Stowage Category	Warning: Flammable liquids. 336 F-E,S-D B
	(Contd. on page 8)



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Trade name: Perma Blue™/AP, Perma Blue™/AP-AUTO, Perma Blue™ Plus/AP, Component 1

	(Contd. of page
Stowage Code	SW2 Clear of living quarters.
14.7 Transport in bulk according to Annex II of and the IBC Code	of Marpol Not applicable.
	**
Transport/Additional information:	The transport regulations are cited according to international regulations and in the form applicable in Germany (GGVSE Possible national deviations in other countries are not considered. THESE TRANSPORT REGULATIONS APPLY TO THE WHOLE PACKAGE!
ADR	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	D/E
IMDG	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 1230 METHANOL SOLUTION, 3 (6.1), II

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Labelling according to Regulation (EC) No 1272/2008 See Section 2.

Hazard pictograms See Section 2.

Signal word See Section 2.

Hazard-determining components of labelling: See Section 2.

Hazard statements See Section 2.

Precautionary statements See Section 2.

Chemical safety assessment A chemical safety assessment was not carried out.

Directive 2012/18/EU

Named dangerous substances - ANNEX I Methanol

Seveso category

H3 STOT SPECÍFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

P5c FLAMMABLE LIQUIDS

Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t $\,$

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

National regulations

Information about limitation of use:

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

Take note of the directive on the safety and health at work for pregnant and breast feeding mothers and workers of childbearing age in the latest version.

Class	Share in %
I	50.0

Water hazard class: Void.



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Trade name: Perma Blue™/AP, Perma Blue™/AP-AUTO, Perma Blue™ Plus/AP, Component 1

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15.2 Chemical safety assessment: A chemical safety assessment has not been carried out.

SECTION 16: Other information

All information and recommodations are believed to be correct as of the date of this Safety Data Sheet but shall not be taken to be all inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. medac shall not be held liable for any damage resulting from handling or from contact with the above product.

Relevant phrases

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

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

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de

Replaces version from:

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 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



phone: 001 925 484-3350

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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: Perma Blue™/AP, Perma Blue™/AP-AUTO, Perma Blue™ Plus/AP, Component 2

Article number: K058B Comp2

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: Uses advised against:

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

1.3 Details of the supplier of the safety data sheet

Manufacturer/Distributor:

Manufacturer:

Diagnostic BioSystems, Inc.

6616 Owens Drive

Pleasanton, CA 94588, USA

Distributor: medac GmbH Theaterstr. 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

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.

Repr. 1B H360FD May damage fertility. May damage the unborn child.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms





GHS07 GHS08

Signal word Danger

Hazard-determining components of labelling:

2-methoxyethanol

Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-500-7] und 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)

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Trade name: Perma Blue™/AP, Perma Blue™/AP-AUTO, Perma Blue™ Plus/AP, Component 2

(Contd. of page 1)

Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H360FD May damage fertility. May damage the unborn child.

Precautionary statements

Obtain special instructions before use. P201

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves / protective clothing / eye protection

P302+P352 IF ON SKIN: Wash with plenty of water.

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

easy to do. Continue rinsing.

Store locked up.

Labelling of packages where the contents do not exceed 125 ml

Hazard pictograms





GHS07 GHS08

Signal word Danger

Hazard-determining components of labelling:

2-methoxyethanol

Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-500-7] und 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)

Hazard statements

H317 May cause an allergic skin reaction.

H360FD May damage fertility. May damage the unborn child.

Precautionary statements

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P405 Store locked up.

2.3 Other hazards

Results of PBT and vPvB assessment

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

SECTION 3: Composition/information on ingredients 3.2 Chemical characterisation: Mixtures **Description:** Water based solution **Dangerous components:** CAS: 109-86-4 2-methoxyethanol 3-5% Flam. Liq. 3, H226 Repr. 1B, H360FD EINECS: 203-713-7 Index number: 603-011-00-4 RTECS: KL 5775000 Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332 Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-0.06-<0.1% 500-7] und 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1) Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331 Skin Corr. 1B, H314 \& Aquatic Acute 1, H400; Aquatic Chronic 1, H410 🏠 Skin Sens. 1, H317 SVHC

109-86-4 2-methoxyethanol

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Trade name: Perma Blue™/AP, Perma Blue™/AP-AUTO, Perma Blue™ Plus/AP, Component 2

(Contd. of page 2)

Additional information For the wording of the listed H-phrases please refer to Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information First aider: Take care of self-protection.

After inhalation Supply fresh air; consult doctor in case of symptoms.

After skin contact

Remove contaminated clothes.

Instantly wash with cupious amounts of water.

In case of symptoms call a physician.

After eve contact

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

Consult ophthalmologist.

After swallowing

Let rinse out mouth and then drink plenty of water.

Call doctor.

4.2 Most important symptoms and effects, both acute and delayed

To the best of our knowledge both acute and delayed symptoms and effects due to improper handling of this preparation have not been investigated.

Information for doctor

Show Safety Data Sheet.

Treatment according to symptoms.

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 substance no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

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

In the event of fire may develop:

Carbon monoxide (CÓ)

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

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.

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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.

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.

Requirements to be met by storerooms and containers:

Store container tightly closed.

Store at +2 °C to +8 °C.

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

Further information about storage conditions:

Store in a locked cabinet or with access restricted to technical experts or their assistants.

Storage class

Storage class 12 according to the German "Technical Rules for Hazardous Substances (TRGS) 510": Noncombustible liquids.

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:

109-86-4 2-methoxyethanol

WEL Long-term value: 3 mg/m³, 1 ppm

Sk

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.

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

Breathing equipment: Not required.

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Protection of hands:

Protective gloves (AQL 1.5).

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

Material of gloves Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

Product quality must comply with standard EN 374.

Penetration time of glove material Breakthrough 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. Penetration time > 120 min.

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.

Void.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical propert	9.1 Information	on on basic r	ohysical and	chemical	propertie
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General Information

Appearance:

Form: liquid
Colour: Colourless
Smell: Almost odourless.
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:

Ca. 100 °C
Ca. 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:No information available.DensityNo information available.

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Relative densityNo information available.Vapour densityNo information available.Evaporation rateNo information available.

Solubility in / Miscibility with

Water: Miscible

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

Viscosity:

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

Solvent content:

 Organic solvents:
 < 5.0 %</td>

 Water:
 > 90

 Solids content:
 < 1 %</td>

9.2 Other informationNo 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.

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.

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

109-86-4 2-methoxyethanol

Oral	LD50	3400 mg/kg (rat)
Dermal	LD50	2000 mg/kg (rabbit)
Inhalative	LC50/4 h	1500 mg/l (rat)

Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-500-7] und 2-Methyl-2H-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)

Oral	LD50	3350 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rab)
Inhalative	LC50/4 h	0.33 mg/l (rat)

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

Primary irritant effect:

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

after swallowing: Mucosal irritations in mouth, pharynx, oesophagus, stomach possible.

after inhalation: Irritations possible. **Respiratory or skin sensitisation** May cause an allergic skin reaction.

Other information (about experimental toxicology): No further relevant information available.

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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 May cause allergic reactions.

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

May damage fertility. May damage the unborn child.

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 Mobility in soil due to the liquid status.

Additional ecological information:

General notes: Void.

12.5 Results of PBT and vPvB assessment

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

12.6 Other adverse effects No relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product residues have to disposed of according to the Waste Framework Directive as well as national and regional regulations in each the latest versions.

Uncleaned packagings:

Recommendation: Disposal according to the respective national official regulations.

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:	Not applicable.
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of Marpoland the IBC Code	Not applicable.
Transport/Additional information:	The transport regulations are cited according to international regulations and in the form applicable in Germany (GGVSE Possible national deviations in other countries are not considered. THESE TRANSPORT REGULATIONS APPLY TO THE WHOLE PACKAGE!
UN "Model Regulation":	-

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Labelling according to Regulation (EC) No 1272/2008 See Section 2.

Hazard pictograms See Section 2.

Signal word See Section 2.

Hazard-determining components of labelling: See Section 2.

Hazard statements See Section 2.

Precautionary statements See Section 2.

Chemical safety assessment A chemical safety assessment was not carried out.

Directive 2012/18/EU

 $\textbf{Named dangerous substances - ANNEX I} \ \text{Contains none of the listed substances}.$

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 30

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	5.0

Water hazard class: Void.

Other regulations, limitations and prohibitive regulations

Substances of very high concern (SVHC) according to REACH, Article 57

109-86-4 2-methoxyethanol

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

H226 Flammable liquid and vapour.

H301 Toxic if swallowed.

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H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H312 Harmful in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

Harmful if inhaled. H332

H360FD May damage fertility. May damage the unborn child.

Very toxic to aquatic life. H400

Very toxic to aquatic life with long lasting effects. H410

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de

Replaces version from:

Abbreviations and acronyms:

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

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

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids - Category 3

Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation - Category 2 Skin Sens. 1: Skin sensitisation - Category 1

Repr. 1B: Reproductive toxicity - Category 1B

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

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

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