

Gesellschaft für klinische Spezialpräparate mbH

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Information about Compilation of Safety Data Sheets

Product: PermaBlue/HRP, Ready To Use 30 ml Company: Diagnostic BioSystems, Inc. Article number: K063

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/HRP Substrate Buffer (Component 2, article number: K063B) and PermaBlue/HRP Chromogen (Component 1, article number: K063C), 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 2018

medac

Product Safety Safety, Health & Environment Phone: +49 (0)4103 8006 0 Fax: +49 (0)4103 8006 100 E-mail: productsafety@medac.de

Theaterstrasse 6 22880 Wedel Germany

Attachment

Geschäftsführer: Jens Denker Jörg Hans Nikolaus Graf Stolberg Heiner Will

Registergericht: Pinneberg HRB 12042 Pl



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

Printing date 18.08.2017

Version number 1

Revision: 18.08.2017

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

1.1 Product identifier

Trade name: PermaBlue™/HRP Component 1

Article number: K063C 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

phone: 001 925 484-3350

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. 3 H226 Flammable liquid and vapour.

Acute Tox. 4 H302 Harmful if swallowed.

Acute Tox. 4 H312 Harmful in contact with skin.

Acute Tox. 4 H332 Harmful if inhaled.

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

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labeled in accordance with Regulation (EC) No 1272/2008 (GHS/CLP).

Hazard pictograms



Signal word Danger

(Contd. on page 2)

GB



Printing date 18.08.2017

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Trade name: PermaBlue™/HRP Component 1

(Contd. of page 1) Hazard-determining components of labelling: 2-methoxyethanol Hazard statements H226 Flammable liquid and vapour. H302+H312+H332 Harmful if swallowed, in contact with skin or if inhaled. 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. Keep away from heat. - No smoking. P210 Wear protective gloves / protective clothing / eye protection P280 P308+P313 IF exposed or concerned: Get medical advice/attention. P405 Store locked up. Labelling of packages where the contents do not exceed 125 ml Hazard pictograms GHS02 GHS07 GHS08 Signal word Danger Hazard-determining components of labelling: 2-methoxyethanol Hazard statements 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. P308+P313 IF exposed or concerned: Get medical advice/attention. 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 Not applicable. Product is a substance. Description: Immunochemical reagent / auxiliary reagent **Dangerous components:** CAS: 109-86-4 2-methoxyethanol 50-100% EINECS: 203-713-7

EINECS: 203-713-7 Index number: 603-011-00-4 RTECS: KL 5775000 RTECS: KL 5775000 RTECS: KL 5775000

SVHC

109-86-4 2-methoxyethanol

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.



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After skin contact Remove contaminated clothes. Instantly wash with cupious 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. Instantly 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 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 (CO_2) 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 vapours/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

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Trade name: PermaBlue™/HRP Component 1

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. Prevent formation of vapour / aerosols. Information about protection against explosions and fires: Protect from heat. Protect against electrostatic charges.

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

Requirements to be met by storerooms and containers:

Store 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 10 (VCI) Flammable 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.

Do not inhale vapours/aerosols.

Remove contaminated clothing immediately.

Avoid contact with the eyes and skin.

Do not eat or drink while working.

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

Breathing equipment:

Essential if vapours/aerosols develop.

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.



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(Contd. of page 4) 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 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 chem	ical properties
General Information	
Appearance:	
Form:	liquid
Colour:	Colourless
Smell:	Sweetish, ether-like
Odour threshold:	No information available.
Important information on protection of healt	th and
environment, and on safety.	No further relevant information available.
pH-value at 20 °C:	7
Change in condition	Not applicable.
Melting point/freezing point:	-85.1 °C
	Ca. 0 °C
Initial boiling point and boiling range:	123 °C
	Ca. 100 °C
Flash point:	37 °C
Inflammability (solid, gaseous)	Not applicable.
Ignition temperature:	310 °C
Decomposition temperature:	No information available.
Self-inflammability:	Not self-inflammable.
Explosive properties:	Product is not explosive. However, formation of explosive air/
	steam mixtures is possible.
Critical values for explosion:	
Lower:	2.4 Vol %
Upper:	20.6 Vol %
Oxidising properties	Not applicable.
Steam pressure at 20 °C:	8 hPa
Density at 20 °C	0.964-0.966 g/cm ³
Relative density	No information available.
Vapour density at 20 °C	33 g/cm ³
Evaporation rate	No information available.



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Trade name: PermaBlue™/HRP Component 1

(Contd. of page 5) Solubility in / Miscibility with Water: Soluble Partition coefficient: n-octanol/water: -0.77 log POW Viscosity: dynamic: No information available. kinematic at 20 °C: 1.6 mm² s (DIN 53211/4) Solvent content: Organic solvents: 99.0 % 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.

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 further relevant information available.

10.4 Conditions to avoid: Heating.

10.5 Incompatible materials: Aluminium. Various plastic materials.

10.6 Hazardous decomposition products: Peroxides. 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

Harmful if swallowed, in contact with skin or if inhaled.

LD/LC50 values that are relevant for classification:

	LD/LC50 values that are relevant for classification:		
109-86-4 2	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)	
Specific s	ymptoms	in biological assay: No further relevant information available.	
Primary ir	ritant effe	ct:	
Skin corre	osion/irrita	ation Based on available data, the classification criteria are not met.	
Serious e	ye damage	e/irritation Based on available data, the classification criteria are not met.	
		armful if swallowed.	
	after inhalation: Harmful if inhaled.		
Respirato	ry or skin	sensitisation Based on available data, the classification criteria are not met.	
Other info	ormation (a	about experimental toxicology): No further relevant information available.	
Subacute	Subacute to chronic toxicity: No further relevant information available.		
Additiona	Additional toxicological information: No further relevant information available.		
Toxicokin	Toxicokinetics, metabolism and distribution No relevant information available.		
Acute effects (acute toxicity, irritation and corrosivity) No acute toxicity information available for this product.			
Sensitisat	Sensitisation No sensitising effect known.		
Repeated	Repeated dose toxicity No further relevant information available.		
CMR effect	CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)		
Germ cell	Germ cell mutagenicity Based on available data, the classification criteria are not met.		

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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 Bioaccumulation is not to be expected.

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: Uncleaned packagings have to be disposed of in the same manner as the product residues.

14.1 UN-Number	
ADR, IMDG, IATA	UN1188
14.2 UN proper shipping name	
ADR	1188 ETHYLENE GLYCOL MONOMETHYL ETHER solution
IMDG, IATA	ETHYLENE GLYCOL MONOMETHYL ETHER solution
14.3 Transport hazard class(es)	
ADR	
Class	3 (F1) Flammable liquids.
Label	3`´



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IMDG, IATA	
	
Class Label	3 Flammable liquids. 3
14.4 Packing group ADR, IMDG, IATA	III
14.5 Environmental hazards: Marine pollutant:	No
14.6 Special precautions for user Kemler Number: EMS Number: Stowage Category	Warning: Flammable liquids. 30 F-E,S-D A
14.7 Transport in bulk according to Annex II and the IBC Code	of Marpol Not applicable.
Transport/Additional information:	The transport regulations are cited according to internation 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) Excepted quantities (EQ) Transport category	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml 3
Tunnel restriction code	D/E
IMDG Limited quantities (LQ) Excepted quantities (EQ)	5L Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
UN "Model Regulation":	UN 1188 ETHYLENE GLYCOL MONOMETHYL ETHER SOLUTION, 3, III

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 Contains none of the listed substances.
Seveso category P5c FLAMMABLE LIQUIDS
Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t



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GP

Trade name: PermaBlue™/HRP Component 1

Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t 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	99.0

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.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H332 Harmful if inhaled.

H360FD May damage fertility. May damage the unborn child.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de

Replaces version from: -

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. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Repr. 1B: Reproductive toxicity – Category 1B



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

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Revision: 01.08.2018

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

1.1 Product identifier

Trade name: PermaBlue™/HRP Component 2

Article number: K063B 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:
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 6616 Owens Drive Pleasanton, CA 94588, USA

Distributor: medac GmbH Theaterstrasse 6 22880 Wedel, Germany Informing department: Product Safety productsafety@medac.de phone: +1 925 484-3350

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

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

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labeled in accordance with Regulation (EC) No 1272/2008 (GHS/CLP).

Hazard pictograms



Signal word Danger

Hazard-determining components of labelling: 2-methoxyethanol

Hazard statements H360FD May damage fertility. May damage the unborn child.



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Trade name: PermaBlue™/HRP Component 2

(Contd. of page 1) **Precautionary statements** P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P308+P313 IF exposed or concerned: Get medical advice/attention. Store locked up. P405 Additional information: Restricted to professional users. Labelling of packages where the contents do not exceed 125 ml Hazard pictograms GHS08 Signal word Danger Hazard-determining components of labelling: 2-methoxyethanol **Hazard statements** H360FD May damage fertility. May damage the unborn child. **Precautionary statements** Restricted to professional users. P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P308+P313 IF exposed or concerned: Get medical advice/attention. 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 Not applicable. Product is a substance. Description: Immunochemical reagent / auxiliary reagent Dangerous components: CAS: 109-86-4 2-methoxyethanol < 20% EINECS: 203-713-7 Flam. Liq. 3, H226
 Repr. 1B, H360FD Index number: 603-011-00-4 RTECS: KL 5775000 Acute Tox. 4, H302; Acute Tox. 4, H312; Acute Tox. 4, H332

SVHC

109-86-4 2-methoxyethanol

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 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.



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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

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 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 is 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 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

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

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Trade name: PermaBlue™/HRP Component 2

(Contd. of page 3)

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

Requirements to be met by storerooms and containers:

Store container tightly closed.

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:

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.

Keep away from food and beverages.

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

Breathing equipment:

Essential if vapours/aerosols develop.

Filter A (according to standard EN 141) for gases and 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 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.

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.

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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:	sweetish, ether-like	
Odour threshold:	No information available.	
Important information on protection of health	n and	
environment, and on safety.	No further relevant information available.	
pH-value at 20 °C:	7	
•	1	
Change in condition	Not applicable.	
Melting point/freezing point:	ca. 0 °C	
Initial boiling point and boiling range:	123 °C	
	ca. 100 °C	
Flash point:	23 - 60 °C	
Inflammability (solid, gaseous)	Not applicable.	
Ignition temperature:	310 °C	
Decomposition temperature:	No information available.	
Self-inflammability:	Not self-inflammable.	
Explosive properties:	Product is not explosive. However, the formation of explosive	
	vapour/air mixtures is possible.	
Critical values for explosion:		
Lower:	2.4 Vol %	
Upper:	20.6 Vol %	
Oxidising properties	Not applicable.	
Steam pressure at 20 °C:	8 hPa	
Density	Not determined.	
Relative density	No information available.	
Vapour density	Not determined.	
Evaporation rate	No information available.	
Solubility in / Miscibility with		
Water:	soluble	
Partition coefficient: n-octanol/water:	-0.77 log POW	
Viscosity:		
dynamic:	No information available.	
kinematic at 20 °C:	$1.6 \text{ mm}^2 \text{ s} (\text{DIN 53211/4})$	
Solvent content:	$1.0 \text{ mm}^2 \text{ 5 (Dm 05211/4)}$	
Organic solvents:	< 20 %	
Water:	< 20 % > 75 %	
Solids content:	<pre>> 75 % < 0.1 %</pre>	
Solius content.		
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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 and stored according to the specifications.

10.3 Possibility of hazardous reactions No further relevant information available.

10.4 Conditions to avoid: Heating.

10.5 Incompatible materials: For these concentrations no further relevant information available.

10.6 Hazardous decomposition products:

Peroxides.

In case of fire of large quantities: 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:

Oral LDso 3400 mg/kg (rat) Dermal LDso 2000 mg/kg (rabbit) Inhalative LCso/4 h 1500 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. Acute effects (acute toxicity, irritation and corrosivity) No acute toxicity 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. <	109-86-4 2	2-methox	yethanol	
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Aspiration hazard Based on available data, the classification criteria are not met.				
	Aspiration	n hazard	Based on available data, the classification criteria are not met.	

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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

Bioaccumulation is not to be expected.

log Pow: -0,77

12.4 Mobility in soil No relevant information available. **Additional ecological information: General notes:** Void.

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 and the IBC Code	of Marpol 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 internatior regulations and in the form applicable in Germany (GGVSI 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. 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	20.0

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

Flammable liquid and vapour. H226 H302 Harmful if swallowed. H312 Harmful in contact with skin. H332 Harmful if inhaled.

H360FD May damage fertility. May damage the unborn child.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de

Replaces version from: 18.08.2017

Reason for alteration: 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

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



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vPvB: very Persistent and very Bioaccumulative Flam. Liq. 3: Flammable liquids – Category 3 Acute Tox. 4: Acute toxicity – Category 4 Repr. 1B: Reproductive toxicity – Category 1B (Contd. of page 8)

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