

Gesellschaft für klinische Spezialpräparate mbH

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# Information about Compilation of Safety Data Sheets

Product: PermaRed™/HRP, Ready To Use 30 ml Company: Diagnostic BioSystems, Inc. Article number: K075

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 PermaRed<sup>™</sup>/HRP Substrate Buffer (Component 2, article number: K 075B), PermaRed<sup>™</sup>/HRP Chromogen (Component 1, article number: K 075C), and PermaRed<sup>™</sup>/HRP Stabilizer Solution (Component 3, article number: K 075ST), 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

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Theaterstrasse 6 22880 Wedel Germany

**Attachment** 

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Registergericht: Pinneberg HRB 12042 PI

Umsatzsteuer ID: DE 118579535



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

Printing date 30.08.2017

Version number 1

Revision: 10.08.2017

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

**1.1 Product identifier** 

Trade name: PermaRed/HRP™ Component 1

Article number: K075C 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: For Research Use. 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

The product is classified according to CLP regulation.

Acute Tox. 4 H312 Harmful in contact with skin.

Acute Tox. 4 H332 Harmful if inhaled.

Eye Irrit. 2 H319 Causes serious eye irritation.

Repr. 1B H360D May damage the unborn child.

# 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is labelled according to Regulation (EC) No. 1272/2008 (GHS/CLP).

Hazard pictograms



Signal word Danger



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(Contd. of page 1) Hazard-determining components of labelling: N,N-dimethylformamide Hazard statements H312+H332 Harmful in contact with skin or if inhaled. Causes serious eye irritation. H319 H360D May damage the unborn child. **Precautionary statements** Do not handle until all safety precautions have been read and understood. P202 IF ON SKIN: Wash with plenty of water. P302+P352 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P405 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: N,N-dimethylformamide Hazard statements H360D May damage the unborn child. Precautionary statements 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** 3.1. Chemical characterisatiion: substances Not applicable. Product is a mixture. 3.2 Chemical characterisation: Mixtures Description: Immunochemical reagent / auxiliary reagent Dangerous components: CAS: 68-12-2 N,N-dimethylformamide 50-100% EINECS: 200-679-5 🚸 Flam. Liq. 3, H226 Index number: 616-001-00-X 🕉 Repr. 1B, H360D

🚯 Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319

# SVHC

RTECS: LQ 2100000

68-12-2 N,N-dimethylformamide

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.



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#### After skin contact

Instantly remove contaminated clothes. 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** Wash out mouth with cupious amounts of water. Let drink water (2 glasses maximum). In case of symptoms call a physician.

# 4.2 Most important symptoms and effects, both acute and delayed

Gastric or intestinal trouble Irritant effects. Information for doctor Show Safety Data Sheet.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment according to symptoms.

# **SECTION 5: Firefighting measures**

### 5.1 Extinguishing media

Suitable extinguishing agents CO<sub>2</sub>, 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

Formation of toxic gases is possible during heating or in case of fire. In the event of fire may develop: Nitrogen oxides (NOx) Carbon dioxide ( $CO_2$ ) Carbon monoxide (CO) **5.3 Advice for firefighters** 

# Protective equipment:

Stay in the danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing. Additional information Precipitate gases/fumes/mists with water spray jet. Collect contaminated fire fighting water separately. It must not enter drains. Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

# **SECTION 6: Accidental release measures**

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:

Avoid reagent contact with eyes and skin.

Provide sufficient ventilation.

Advice for emergency responders: Protective equipment: see Section 8.

6.2 Environmental precautions: Do not empty into drains.

### 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Afterwards clean with water and cleansing agent. Dispose of contaminated material as waste according to Section 13.

### 6.4 Reference to other sections

See Section 7 for information on safe handling See Section 8 for information on personal protection equipment.

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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 danger of explosion.

7.2 Conditions for safe storage, including any incompatibilities

When handling customary laboratory quantities please follow the corresponding laboratory guidelines. Storage

Requirements to be met by storerooms and containers: Store at +2 °C to +8 °C. Information about storage in one common storage facility: Store separately from stong oxidants and halogens. Further information about storage conditions: No further relevant information available. Storage class Please 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:

68-12-2 N,N-dimethylformamide

WEL Short-term value: 30 mg/m<sup>3</sup>, 10 ppm Long-term value: 15 mg/m<sup>3</sup>, 5 ppm

#### Sk

**DNELs** No further relevant information available.

PNECs No further relevant information available.

CAS No. Designation of material % Type Value Unit

Additional Occupational Exposure Limit Values for possible hazards during processing: Not applicable.

Additional information: The official lists that were valid during the compilation were used as basis.

### 8.2 Exposure controls

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See Section 7.

# Personal protective equipment

General protective and hygienic measures The usual precautionary measures should be adhered to in handling the chemicals. Avoid contact with the eyes and skin. Remove contaminated clothing immediately. Do not eat or drink while working. Keep away from food and beverages. Wash hands during breaks and at the end of the work. Breathing equipment: No special precautions are necessary if handled correctly. Protection of hands: Protective gloves (AQL 1.5). Material of gloves Nitrile rubber, NBR Natural rubber, NR Thickness 0.11 mm. The product quality has to comply with DIN EN 455. Penetration time of glove material 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.

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# Trade name: PermaRed/HRP™ Component 1

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**

0.1 Information on basic physical and chamical properties	
9.1 Information on basic physical and chemical properties General Information	
Appearance:	
Form:	liquid
Colour:	No information available.
Smell:	slightly amine-like
Odour threshold:	No information available.
Important information on protection of health an	
environment, and on safety.	No further relevant information available.
· •	
pH-value:	No information available.
Change in condition	Not applicable.
Melting point/freezing point:	No information available.
Flash point:	No informarion available.
Inflammability (solid, gaseous)	Not applicable.
Ignition temperature:	No information available.
Decomposition temperature:	No information available.
Self-inflammability:	Not self-inflammable.
Explosive properties:	Not explosive.
Critical values for explosion:	
Lower:	Not applicable.
Upper:	Not applicable.
Oxidising properties	No information available.
Steam pressure:	No information available.
Density	No information available.
Relative density	No information available.
Vapour density	No information available.
Evaporation rate	No information available.
Solubility in / Miscibility with	
Water:	Fully miscible.
Partition coefficient: n-octanol/water:	<1 log POW
Viscosity:	
dynamic:	No information available.
kinematic:	No information available.
Solvent content:	
Organic solvents:	< 30 %
Water:	> 60 %
Solids content:	< 5 %
9.2 Other information	No further relevant information available.
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# **SECTION 10: Stability and reactivity**

10.1 Reactivity For this mixture no relevant information available.

10.2 Chemical stability The product is chemically stable under the indicated storage conditions.

Thernak decomposition / conditions to be avoided:

No decomposition if used according to specifications.

Conditions to be avoided:

Warming, light.

10.3 Possibility of hazardous reactions For these concentrations no relevant information available.

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 Harmful in contact with skin or if inhaled.

LD/LC50	LD/LC50 values that are relevant for classification:		
68-12-2 N	68-12-2 N,N-dimethylformamide		
Oral	LD50	2800 mg/kg (rat)	
Dermal	LD50	1500 mg/kg (rabbit)	
Inhalative	LC50/4 h	9-15 mg/l (rat)	
Specific s	symptoms	in biological assay: No further relevant information available.	
	ritant effe		
		ation Irritations possible.	
		e/irritation	
	erious eye		
		ucosal irritations in mouth, pharynx and oesophagus possible.	
		ations possible.	
		sensitisation Based on available data, the classification criteria are not met.	
		about experimental toxicology): No further relevant information available.	
	Subacute to chronic toxicity: Danger of cutaneous absorption.		
	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 Hepatopathy.		
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 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.			
Aspiratio			

# **SECTION 12: Ecological information**

12.1 Toxicity

Aquatic toxicity: No further relevant information available.



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12.2 Persistence and degradability No further relevant information available.
Other information: No further relevant information available.
Behaviour in environmental systems:
Components: Accumulation in organisms is not to be expected.

# **12.3 Bioaccumulative potential** log Pow <1

Bioaccumulation is not to be expected.

12.4 Mobility in soil Hogh mobility (source: ECHA). Ecotoxical effects: Remark: Fischtoxizität: LC<sub>50</sub>: Lepomis macrochirus: 6300 mg/l / 96h. LC<sub>50</sub>: Onchorhynchus mykiss: 9800 mg/l / 96h. LC<sub>50</sub>: Plimephales promelas: 10600 mg/l / 96h. Daphnientoxizität: LC<sub>50</sub>: Daphnia magna: 15700 mg/l / 48h.

Algentoxizität:

 $LC_{50}$ : Desmodesmus subspicatus IC50 > 500 mg/l / 96h.

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 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.	
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14.7 Transport in bulk according to Annex II of Marpol		
and the IBC Code	Not applicable.	
Transport/Additional information:	Not classified as dangerous in the meaning of transport regulations as issued in the latest version.	
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 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.

Directive 2012/18/EU Named dangerous substances - ANNEX I None of the ingredients is listed. 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.

Water hazard class: Void.

Other regulations, limitations and prohibitive regulations Void. Substances of very high concern (SVHC) according to REACH, Article 57 68-12-2 N,N'-dimethylformamide

68-12-2 N,N-dimethylformamide

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.

H312 Harmful in contact with skin.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H360D 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



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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 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2 Repr. 1B: Reproductive toxicity – Category 1B



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phone: 001 925 484-3350

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

1.1 Product identifier

Trade name: PermaRed/HRP™ Component 2

Article number: K075B 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: For Research Use. Sector of Use SU20 Health services 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

According to Regulation (EC) No. 1272/2008 the mixture is classified as hazardous.

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.

### 2.2 Label elements

### Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms



#### Signal word Warning

### Hazard-determining components of labelling:

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: PermaRed/HRP™ Component 2

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Hazard statements

H315 Causes skin irritation. H319 Causes serious eye irritation. H317 May cause an allergic skin reaction.

#### Precautionary statements

P202Do not handle until all safety precautions have been read and understood.P280Wear protective gloves / protective clothing / eye protectionP302+P352IF 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.

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



Signal word Warning

#### Hazard-determining components of labelling:

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.

# **Precautionary statements**

P202Do not handle until all safety precautions have been read and understood.P280Wear protective gloves / protective clothing / eye protectionP302+P352IF ON SKIN: Wash with plenty of soap and water.P305+P351+P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

### 2.3 Other hazards Void.

Results of PBT and vPvB assessment

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

# **SECTION 3: Composition/information on ingredients**

**3.1. Chemical characterisatiion: substances** Not applicable. Product is a mixture.

# 3.2 Chemical characterisation: Mixtures

Description: Water based solution

# Dangerous components:

Gemisch aus/Mixture of: 5-Chlor-2-methyl-2H-isothiazol-3-on [EG-Nr. 247-500-7] und 2-Methyl-2H-	0.06-<0.1%
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	
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; consult doctor in case of symptoms.



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After skin contact Remove contaminated clothes. Clean contaminated areas with water and soap. 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. Consult ophthalmologist. After swallowing Rinse out mouth. Let drink water (2 glasses maximum). In case of disorders consult doctor.

# **4.2 Most important symptoms and effects, both acute and delayed** No further televant 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** Product itself does not burn. Use fire fighting measures that suit the environment. **For safety reasons unsuitable extinguishing agents** For this mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture No further relevant information available.

### 5.3 Advice for firefighters

#### Protective equipment:

In case of burning of a larger amount:

Stay in the danger area only with self-contained breathing apparatus.

Prevent skin and eye contact by keeping a safe distance or by wearing suitable protective clothing.

#### Additional information

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

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

# **SECTION 6: Accidental release measures**

### 6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:

Avoid reagent contact with eyes and skin.

Advice for emergency responders: Protective equipment: see Section 8.

6.2 Environmental precautions: Do not allow product to reach sewage system or water bodies.

#### 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Afterwards clean with water and cleansing agent. Dispose of contaminated material as waste according to Section 13. 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.

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GB

# **SECTION 7: Handling and storage**

**7.1 Precautions for safe handling** No special precautions necessary if handled correctly. **Information about protection against explosions and fires:** No special measures required.

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

Requirements to be met by storerooms and containers: Store at +2 °C to +8 °C.

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

Further information about storage conditions: The indications are valid for the whole package. Storage class

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: **DNELs** Not applicable. **PNECs** Not applicable. Ingredients with biological limit values: Void. CAS No. Designation of material % Type Value Unit Additional Occupational Exposure Limit Values for possible hazards during processing: Not applicable. Additional information: The official lists that were valid during the compilation were used as basis. 8.2 Exposure controls Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. See Section 7. Personal protective equipment General protective and hygienic measures The usual precautionary measures should be adhered to in handling the chemicals. Avoid contact with the eyes and skin. Remove contaminated clothing immediately. Do not eat or drink while working. Keep away from food and beverages. Wash hands during breaks and at the end of the work. Breathing equipment: Not required. Protection of hands: Disposable medical gloves (AQL 1.5). Material of gloves Nitrile rubber, NBR Natural rubber, NR Thickness 0.11 mm. The product quality has to comply with DIN EN 455. Penetration time of glove material Not applicable. For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable: Product has not been designed for permanent contact. For the permanent contact gloves made of the following materials are suitable: Product has not been designed for permanent contact. For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable: Product has not been designed for permanent contact. As protection from splashes gloves made of the following materials are suitable: Nitrile rubber, NBR Natural rubber, NR Thickness: 0.11 mm. (Contd. on page 5)



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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:	No information available.
Smell:	No information available.
Odour threshold:	No information available.
pH-value:	No information available.
Change in condition	
Melting point/freezing point:	No information available.
Initial boiling point and boiling range	<b>ie:</b> No information available.
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:	Not explosive.
Lower:	Not applicable.
Upper:	Not applicable.
	Not applicable. Not oxidizing.
Oxidising properties	No information available.
Steam pressure:	No information available.
Density Relative density	
Relative density	No information available.
Vapour density	No information available.
Evaporation rate	No information available.
Solubility in / Miscibility with Water:	Fully missible
Partition coefficient: n-octanol/water:	Fully miscible.
	No information available.
Viscosity:	No information quailable
dynamic: kinematic:	No information available.
	No information available.
Solvent content:	0.0.9/
Organic solvents:	0.0 %
Water:	98 %
Solids content:	2.0 %
9.2 Other information	No further relevant information available.

# **SECTION 10: Stability and reactivity**

**10.1 Reactivity** For this mixture no relevant information available.

**10.2 Chemical stability** The product is chemically stable under the indicated storage conditions. **Thernak decomposition** / **conditions to be avoided:** No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions No dangerous reactions known.

**10.4 Conditions to avoid:** No further relevant information available.



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

# 10.6 Hazardous decomposition products:

For this/these concentartion/s no dangerous products of decomposition known.

# **SECTION 11: Toxicological information**

11.1 Information on toxicological effects Acute toxicity Based on available data, the classification criteria are not met. LD/LC50 values that are relevant for classification: Quantitative data about toxicity of this product are not available. Primary irritant effect: Skin corrosion/irritation Causes skin irritation. Serious eye damage/irritation Causes serious eye irritation. after swallowing: Slight mucosal irritations in mouth, pharynx and oesophagus possible. after inhalation: No irritant effects known. Respiratory or skin sensitisation May cause an allergic skin reaction. CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) Germ cell mutagenicity Based on available data, the classification criteria are not met. Carcinogenicity Based on available data, the classification criteria are not met. Reproductive toxicity Based on available data, the classification criteria are not met. STOT-single exposure Based on available data, the classification criteria are not met. STOT-repeated exposure Based on available data, the classification criteria are not met.

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

# SECTION 12: Ecological information

# 12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential Bioaccumulation is not to be expected.

12.4 Mobility in soil No relevant information available.

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.

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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:	Not applicable.
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of Marpol         and the IBC Code       Not applicable.	
Transport/Additional information:	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!
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 Not applicable. Signal word Not applicable.

Hazard-determining components of labelling: Not applicable.
Hazard statements Not applicable.
Precautionary statements Not applicable.
Chemical safety assessment A chemical safety assessment was not carried out.

Directive 2012/18/EU Named dangerous substances - ANNEX I None of the ingredients is listed. 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 safety and health at work for pregnant and breast feeding mothers and workers of childbearing age in the latest version. Take note of the directive on the protection of young people at work in the latest version.

Water hazard class: Void.

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

# **SECTION 16: Other information**

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



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(Contd. of page 7) **Relevant phrases** H301 Toxic if swallowed. H311 Toxic in contact with skin. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H331 Toxic if inhaled. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects. 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 CAS: Chemical Abstracts Service (division of the American Chemical Society) DNEL: Derived No-Effect Level (REACH) PNEC: Predicted No-Effect Concentration (REACH) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic SVHC: Substances of Very High Concern vPvB: very Persistent and very Bioaccumulative Acute Tox. 3: Acute toxicity – Category 3 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 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 GB



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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: PermaRed/HRP™ Component 3

Article number: K075ST Comp3

#### 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: 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

Acute Tox. 4 H302 Harmful if swallowed.

Eye Irrit. 2 H319 Causes serious eye irritation.

# 2.2 Label elements Labelling according to Regulation (EC) No 1272/2008





Signal word Warning

#### Hazard-determining components of labelling: 3-Methyl-2-benzothiazolinone hydrazone hydrochloride hydrate

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#### Trade name: PermaRed/HRP™ Component 3

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#### Hazard statements

H302 Harmful if swallowed. H319 Causes serious eye irritation.

# **Precautionary statements**

P280 Wear protective gloves / protective clothing / eye protection

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

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



Signal word Warning

#### Hazard-determining components of labelling:

3-Methyl-2-benzothiazolinone hydrazone hydrochloride hydrate

# 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 characterisatiion: substances Not applicable. Product is a mixture.

3.2 Chemical characterisation: Mixtures

**Description:** Water based solution

# Dangerous components:

3-Methyl-2-benzothiazolinone hydrazone hydrochloride hydrate

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; consult doctor in case of symptoms.

# After skin contact

Remove contaminated clothes.

Instantly rinse with water. In case of symptoms call a physician.

After eye contact

Alter eye 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. In case of disorders consult doctor.

**4.2 Most important symptoms and effects, both acute and delayed** No further televant information available. **Information for doctor** 

#### Show Safety Data Sheet.

Treatment according to symptoms.

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25-50%

Acute Tox. 3, H301 Eye Irrit. 2, H319



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Danger No further relevant information available.

#### 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

# **SECTION 5: Firefighting measures**

### 5.1 Extinguishing media

Suitable extinguishing agents Product itself does not burn. Use fire fighting measures that suit the environment. For safety reasons unsuitable extinguishing agents For this mixture no limitations of extinguishing agents are given.

### 5.2 Special hazards arising from the substance or mixture

In the event of fire formation of toxic gases possible. In the event of fire may develop: Carbon monoxide (CO) Carbon dioxide (CO<sub>2</sub>) Nitrogen oxides (NOx)

### 5.3 Advice for firefighters

# **Protective equipment:**

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. 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.

Prevent contact with skin and eyes.

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

# 7.2 Conditions for safe storage, including any incompatibilities

Storage Requirements to be met by storerooms and containers: Store container tightly closed in cool location. Store at +2 °C to +8 °C. Information about storage in one common storage facility: Not required. Further information about storage conditions: Protect from heat and direct sunlight. Protect from freezing.



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#### Trade name: PermaRed/HRP™ Component 3

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:

Not required according to German regulations.

**DNELs** No further relevant information available.

**PNECs** No further relevant information available.

CAS No. Designation of material % Type Value Unit

Additional Occupational Exposure Limit Values for possible hazards during processing: Not applicable.

Additional information: The official lists that were valid during the compilation were used as basis.

# 8.2 Exposure controls

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See Section 7.

# Personal protective equipment

# General protective and hygienic measures

The usual precautionary measures should be adhered to in handling the chemicals.

Avoid contact with the eyes and skin.

Remove contaminated clothing immediately.

Do not eat or drink while working.

Keep away from food and beverages.

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

Breathing equipment: Not required.

#### Protection of hands:

Disposable medical gloves (AQL 1.5).

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

#### Material of gloves

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

The product quality has to comply with DIN EN 455.

Penetration time of glove material Not applicable.

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

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable: Product has not been designed for permanent contact.

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

Nitrile rubber, NBR

Natural rubber, NR

Thickness: 0.11 mm.

Eye protection: Safety glasses (standard EN 166).

Body protection: Protective work clothing.

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

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Risk management measures Void.

# **SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical proper         General Information         Appearance:         Form:       liquid         Colour:       Colourless         Smell:       No information         Odour threshold:       No information         pH-value:       No information         Change in condition       No information	available. available.
Appearance:       liquid         Form:       liquid         Colour:       Colourless         Smell:       No information         Odour threshold:       No information         pH-value:       No information         Change in condition       Mo information         Melting point/freezing point:       No information	available.
Form:liquidColour:ColourlessSmell:No informationOdour threshold:No informationpH-value:No informationChange in condition Melting point/freezing point:No information	available.
Colour:ColourlessSmell:No informationOdour threshold:No informationpH-value:No informationChange in condition Melting point/freezing point:No information	available.
Smell:     No information       Odour threshold:     No information       pH-value:     No information       Change in condition     Mo information       Melting point/freezing point:     No information	available.
Odour threshold:       No information         pH-value:       No information         Change in condition       No information         Melting point/freezing point:       No information	available.
pH-value:       No information         Change in condition       Molting point/freezing point:       No information	
Change in condition Melting point/freezing point: No information	available.
Melting point/freezing point: No information	
Melting point/freezing point: No information	
	available.
Initial boiling point and boiling range: No information	available.
Flash point: Not applicable.	
Inflammability (solid, gaseous) Not applicable.	
Ignition temperature: Not available.	
Decomposition temperature: No information	available
Self-inflammability: Not self-inflammability:	
Explosive properties: Not explosive.	
Critical values for explosion:	
Lower: Not applicable.	
Upper: Not applicable.	
Oxidising properties Not applicable.	
Steam pressure: No information	available
Density No information	
Relative density No information	
Vapour density No information	
Evaporation rate Not determined	
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: 0.0 %	
Water: 50.0 %	
Solids content: < 50 %	
9.2 Other information No further relev	ant information available.

# **SECTION 10: Stability and reactivity**

10.1 Reactivity The mixture is chemically not reactive.

**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: Heating.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: In case of burning of larger amounts: See Section 5.

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Trade name: PermaRed/HRP™ Component 3

Additional information: No further relevant information available.

# **SECTION 11: Toxicological information**

11.1 Information on toxicological effects		
Acute toxicity		
Harmful if swallowed.		
LD/LC50 values that are relevant for classification:		
3-Methyl-2-benzothiazolinone hydrazone		
hydrochloride hydrate		
Oral LD50 149 mg/kg (rat)		
Dermal LD50 12300 mg/kg (rabbit)		
Specific symptoms in biological assay: No further relevant information available.		
Primary irritant effect:		
Skin corrosion/irritation Based on available data, the classification criteria are not met.		
Serious eye damage/irritation		
Causes serious eye irritation.		
after swallowing: Harmful if swallowed.		
after inhalation: Slight irritations possible.		
Respiratory or skin sensitisation Based on available data, the classification criteria are not met.		
Other information (about experimental toxicology): No further relevant information available.		
Subacute to chronic toxicity: No further relevant information available.		
Additional toxicological information: No further relevant information available.		
Toxicokinetics, metabolism and distribution No relevant information available.		
Acute effects (acute toxicity, irritation and corrosivity) No acute toxicity information available for this product.		
Sensitisation No sensitising effect known.		
Repeated dose toxicity No further relevant information available.		
CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)		
Germ cell mutagenicity Based on available data, the classification criteria are not met.		
Carcinogenicity Based on available data, the classification criteria are not met.		
Reproductive toxicity Based on available data, the classification criteria are not met.		
STOT-single exposure Based on available data, the classification criteria are not met.		
STOT-repeated exposure Based on available data, the classification criteria are not met.		
Aspiration hazard Based on available data, the classification criteria are not met.		
SECTION 12: Ecological information		

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

**12.2 Persistence and degradability** No further relevant information available. **Other information:** No further relevant information available.

12.3 Bioaccumulative potential Bioaccumulation is not to be expected.

12.4 Mobility in soil Mobility in soil due to the liquid status. Ecotoxical effects: Remark: There are no ecotoxicological assessments. 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.

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# **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	-
14.4 Packing group ADR, IMDG, IATA	-
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.	
Transport/Additional information:	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 Named dangerous substances - ANNEX I Contains none of the listed substances. REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

# National regulations

### Information about limitation of use:

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



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### Trade name: PermaRed/HRP™ Component 3

Water hazard class: Void.

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

# **SECTION 16: Other information**

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

# **Relevant phrases**

H301 Toxic if swallowed. H319 Causes serious eye irritation.

#### 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

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

Eye Irrit. 2: Serious eye damage/eye irritation - Category 2

GB