

Information about Compilation of Safety Data Sheets

Product: PermaRed/AP-AutoPlus, Ready To Use 110 ml
Company: Diagnostic BioSystems, Inc.
Article number: K057-AUTOPLUS-110

All components of the aforementioned kit had been classified according to Regulation (EC) No. 1907/2006 (REACH) and to Regulation (EC) No. 1272/2008 (GHS/CLP).

For the kit component PermaRed/AP-AutoPlus Substrate Buffer (Component 2, article number: K 057B), a Safety Data Sheet had been compiled (enclosure).
For the other kit component PermaRed/AP-AutoPlus Chromogen (Component 1, article number: K 057C), no Safety Data Sheet is required after classification according to the Regulation (EC) No. 1907/2006 (REACH) and the Regulation (EC) No. 1272/2008 (GHS/CLP).

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

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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 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

phone: 001 925 484-3350

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**

GHS07

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)

(Contd. on page 2)

GB

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

Printing date 30.08.2017

Version number 1

Revision: 10.08.2017

Trade name: PermaRed/HRP™ Component 2

(Contd. of page 1)

Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

Precautionary statements

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

P280 Wear protective gloves / protective clothing / eye protection

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

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

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

GHS07

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

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

P280 Wear protective gloves / protective clothing / eye protection

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

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 characterisation: 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-isothiazol-3-on [EG-Nr. 220-239-6] (3:1)

0.06-<0.1%

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.

(Contd. on page 3)

GB

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

Printing date 30.08.2017

Version number 1

Revision: 10.08.2017

Trade name: PermaRed/HRP™ Component 2

(Contd. of page 2)

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 relevant information available.

Information for doctor

Show Safety Data Sheet.
Treatment according to symptoms.

Danger No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing agents 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.

GB

(Contd. on page 4)

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

Printing date 30.08.2017

Version number 1

Revision: 10.08.2017

Trade name: PermaRed/HRP™ Component 2

(Contd. of page 3)

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
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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)

GB

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

Printing date 30.08.2017

Version number 1

Revision: 10.08.2017

Trade name: PermaRed/HRP™ Component 2

(Contd. of page 4)

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:	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:	
Lower:	Not applicable.
Upper:	Not applicable.
Oxidising properties	Not oxidizing.
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:	No information available.
Viscosity:	
dynamic:	No information available.
kinematic:	No information available.
Solvent content:	
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.

Thermal 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.

(Contd. on page 6)

GB

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

Printing date 30.08.2017

Version number 1

Revision: 10.08.2017

Trade name: PermaRed/HRP™ Component 2

(Contd. of page 5)

10.5 Incompatible materials: For these concentrations no further relevant information available.**10.6 Hazardous decomposition products:**

For this/these concentration/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 (carcinogenicity, 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 be disposed of according to the Waste Framework Directive as well as national and regional regulations in each of the latest versions.

Uncleaned packagings:**Recommendation:** Disposal according to the respective national official regulations.GB
(Contd. on page 7)

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

Printing date 30.08.2017

Version number 1

Revision: 10.08.2017

Trade name: PermaRed/HRP™ Component 2

(Contd. of page 6)

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 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 recommendations 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.

(Contd. on page 8)

GB

**Safety data sheet
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Printing date 30.08.2017

Version number 1

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Trade name: PermaRed/HRP™ Component 2

(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