

Information about Compilation of Safety Data Sheets

Product: PermaRed/AP-AutoPlus, Ready To Use 30 ml
Company: Diagnostic BioSystems, Inc.
Article number: K057-AUTOPLUS

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 10.08.2017

Version number 1

Revision: 08.08.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** PermaRed/AP, PermaRed/AP-Auto, PermaRed/AP-AutoPlus, Component 2**Article number:** K049B Comp2, K57B Comp2**Registration number**

The dangerous components are a mixture of several substances (see chapter 3). Registration numbers are not available for these substances as the substances or 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**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

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**

Skin Sens. 1 H317 May cause an allergic skin reaction.

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

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

P280 Wear protective gloves / protective clothing / eye protection

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

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

P280 Wear protective gloves / protective clothing / eye protection

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

2.3 Other hazards**Results of PBT and vPvB assessment****PBT:** Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.**vPvB:** Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

SECTION 3: Composition/information on ingredients

3.1. Chemical characterisation: substances Not applicable. Product is a mixture.**3.2 Chemical characterisation: Mixtures****Description:** Water based solution**Dangerous components:**

CAS: 7647-01-0 EINECS: 231-595-7 Index number: 017-002-00-2 RTECS: MW 9620000	hydrogen chloride ⚠ Skin Corr. 1B, H314 ⚠ STOT SE 3, H335	0.1-<0.5%
	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) ⚠ Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331 ⚠ Skin Corr. 1B, H314 ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410 ⚠ Skin Sens. 1, H317	0.0015-<0.05%

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.

Seek medical treatment in case of complaints.

After skin contact

Remove contaminated clothes.

Instantly wash with water and soap and rinse thoroughly.

In case of symptoms call a physician.

After eye contact

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

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In case of onset of symptoms consult doctor.

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 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

In the event of fire formation of toxic gases possible.

In the event of fire may develop:

Carbon dioxide (CO₂)

Carbon monoxide (CO)

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 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:

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

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.

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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** No further relevant information available.**Storage****Requirements to be met by storerooms and containers:**

Store container tightly closed in cool, properly ventilated 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.

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:****7647-01-0 hydrogen chloride**

WEL	Short-term value: 8 mg/m ³ , 5 ppm Long-term value: 2 mg/m ³ , 1 ppm (gas and aerosol mists)
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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.

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

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

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

Nitrile rubber, NBR

Natural rubber, NR

Thickness: 0.11 mm.

Eye protection: Safety glasses (standard EN 166).

Body protection: Protective work clothing.

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

Risk management measures Void.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form:	liquid
Colour:	Transparent
Smell:	Odourless
Odour threshold:	Not determined.

Important information on protection of health and environment, and on safety.

No further relevant information available.

pH-value at 20 °C: 8.6

Change in condition

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

Flash point:	Not applicable.
Inflammability (solid, gaseous)	Not applicable.
Ignition temperature:	Not available.
Decomposition temperature:	No information available.
Self-inflammability:	Not self-inflammable.
Explosive properties:	Not explosive.
Critical values for explosion:	
Lower:	Not applicable.
Upper:	Not applicable.
Oxidising properties	Not applicable.
Steam pressure at 20 °C:	23 hPa
Density at 20 °C	1.00 g/cm ³
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Fully miscible.
Partition coefficient: n-octanol/water:	Not applicable.
Viscosity:	
dynamic:	Not determined.
kinematic:	Not determined.
Solvent content:	
Organic solvents:	< 0.6 %
Water:	98 %
Solids content:	< 2 %

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9.2 Other information

No further relevant 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.**Thermal 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:**

Strong acids.
Strong bases.
Strong oxidising agents
Metals.
Metallic compounds.

10.6 Hazardous decomposition products: No further relevant information available.**Additional information:** No further relevant information available.**SECTION 11: Toxicological information****11.1 Information on toxicological effects** Data on the toxicity of this mixture are not available.**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.**Specific symptoms in biological assay:** No further relevant information available.**Primary irritant effect:****Skin corrosion/irritation** Slight irritations possible.**Serious eye damage/irritation** Slight irritations possible.**after swallowing:** Slight mucosal irritations in mouth, pharynx and oesophagus possible.**after inhalation:** Slight irritations possible.**Respiratory or skin sensitisation**

May cause an allergic skin reaction.

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** May cause sensitisation by skin contact.**Repeated dose toxicity** No further relevant information available.**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** No information available.**Aquatic toxicity:** No further relevant information available.**12.2 Persistence and degradability** No further relevant information available.**Other information:** No further relevant information available.

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Behaviour in environmental systems:
Components: Accumulation in organisms is not to be expected.

12.3 Bioaccumulative potential Bioaccumulation is not to be expected.

12.4 Mobility in soil No data available.

Ecotoxicological effects:
Remark: No further relevant information available.

Additional ecological information:
General notes:

At present there are no ecotoxicological assessments.

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 of 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 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":

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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.

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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** hydrogen chloride**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.

Water hazard class: Void.**Other regulations, limitations and prohibitive regulations** Void.**Substances of very high concern (SVHC) according to REACH, Article 57** Not applicable.**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.

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.

H335 May cause respiratory irritation.

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:**

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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

Acute Tox. 3: Acute toxicity – Category 3

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

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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