

## Information about Compilation of Safety Data Sheets

**Product: PermaGreen Plus/AP**, Ready To Use 110 ml  
**Company: Diagnostic BioSystems, Inc.**  
**Article number: K059-110**

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

For the kit components PermaGreen Plus/AP Chromogen (Component 1, article number: K 059C) and PermaGreen Plus/AP Substrate Buffer (Component 2, article number: K 059B), Safety Data Sheets had been compiled (enclosure).

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

Date of issue: August 2017

**medac**

Product Safety

Safety Health Environment

Phone: +49 (0)4103 8006 0

Fax: +49 (0)4103 8006 100

E-mail: productsafety@medac.de

Theaterstrasse 6  
22880 Wedel  
Germany

Attachment

Geschäftsführer:

Jens Denker

Dr. Rainer Dickhardt

Jörg Hans

Dr. Ulrich Kosciessa

Nikolaus Graf Stolberg

Heiner Will

Registergericht:

Pinneberg HRB 12042 PI

Umsatzsteuer ID:

DE 118579535

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

Printing date 16.08.2017

Version number 1

Revision: 16.08.2017

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** Perma Green™/AP, Perma Green™ Plus/AP Component 1**Article number:** K052C Comp1, K059C Comp 1**Registration number**

This product is a mixture (see chapter 3). Registration number(s) is/are not available for this substance/these substances as the substance(s) or its/their use are exempted from registration according to Article 2 REACH Regulation (EC) No. 1907/2006, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Relevant identified uses:

For in vitro diagnosis.

Uses advised against:

No further relevant information available.

**Sector of Use** SU20 Health services**Product category** PC21 Laboratory chemicals**Process category** PROC15 Use as laboratory reagent**Application of the substance / the mixture** Immunochemical reagent for detection / auxiliary reagent**1.3 Details of the supplier of the safety data sheet****Manufacturer/Distributor:**

Manufacturer:

Diagnostic BioSystems, Inc.

6616 Owens Drive

Pleasanton, CA 94588, USA

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**

Flam. Liq. 3 H226 Flammable liquid and vapour.

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

**2.2 Label elements****Labelling according to Regulation (EC) No 1272/2008****Hazard pictograms**

GHS02 GHS08

**Signal word** Danger**Hazard-determining components of labelling:**

Methanol

**Hazard statements**

H226 Flammable liquid and vapour.

(Contd. on page 2)

GB

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

Printing date 16.08.2017

Version number 1

Revision: 16.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 1

(Contd. of page 1)

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

**Precautionary statements**

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

P280 Wear protective gloves / protective clothing / eye protection

P308 IF exposed or concerned:

P310 Immediately call a POISON CENTER/doctor.

P405 Store locked up.

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

GHS02 GHS08

**Signal word** Danger**Hazard-determining components of labelling:**

Methanol

**Hazard statements**

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

**Precautionary statements**

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

P280 Wear protective gloves / protective clothing / eye protection

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

P405 Store locked up.

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

### SECTION 3: Composition/information on ingredients

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

|                            |  |        |
|----------------------------|--|--------|
| CAS: 67-56-1               | Methanol   | 25-50% |
| EINECS: 200-659-6          | Flam. Liq. 2, H225   |        |
| Index number: 603-001-00-X | Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331 |        |
| RTECS: PC 1400000          | STOT SE 1, H370  |        |

**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.

Rinse well with water immediately.

Call a doctor immediately.

**After eye contact**

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

Call a doctor immediately.

(Contd. on page 3)

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

Printing date 16.08.2017

Version number 1

Revision: 16.08.2017

**Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 1**

(Contd. of page 2)

**After swallowing**

Let rinse out mouth and then drink plenty of water.  
Call a doctor immediately.

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

Irritant effects.  
Breathing difficulty  
Nausea  
Visual disorders.  
Risk of serious eye damage.  
Blindness.  
Drying-out effect resulting in rough and chapped skin.

**Information for doctor**

Show Safety Data Sheet.  
Treatment according to symptoms.

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

No further relevant information available.

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

**Suitable extinguishing agents** 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**

Combustible.  
Vapours are heavier than air and may spread along floors.  
In the event of fire may develop:  
Carbon monoxide (CO)  
Carbon dioxide (CO<sub>2</sub>)  
Nitrogen oxides (NO<sub>x</sub>)  
Formaldehyde

**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:  
Do not inhale vapours/aerosols.  
Avoid substance contact with skin and eyes.  
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).  
Dispose of the material collected according to respective national regulations.  
Afterwards clean with water and cleansing agent.  
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.

(Contd. on page 4)

GB

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

Printing date 16.08.2017

Version number 1

Revision: 16.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 1

See Section 13 for information on disposal.

(Contd. of page 3)

### SECTION 7: Handling and storage

**7.1 Precautions for safe handling** Open and handle container with care.**Information about protection against explosions and fires:**

Keep away from open flames, hot surfaces and sources of ignition.

Protect against electrostatic charges.

**7.2 Conditions for safe storage, including any incompatibilities****Storage****Requirements to be met by storerooms and containers:**

Store tightly closed, apart from ignition and heat sources.

Store at +2 °C to +8 °C.

**Information about storage in one common storage facility:** Not required.**Further information about storage conditions:**

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

**Storage class** See the respective national guidelines.**7.3 Specific end use(s)** Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

### SECTION 8: Exposure controls/personal protection

**Additional information about design of technical systems:** No further data; see Section 7.**8.1 Control parameters****Components with critical values that require monitoring at the workplace:****67-56-1 Methanol**

|     |   |
|-----|---|
| WEL | Short-term value: 333 mg/m <sup>3</sup> , 250 ppm |
|     | Long-term value: 266 mg/m <sup>3</sup> , 200 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.

Do not inhale aerosols.

Avoid contact with the eyes and skin.

Remove contaminated clothing immediately.

Do not eat or drink while working.

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

**Breathing equipment:** Essential if vapours/aerosols develop.**Protection of hands:**

Protective gloves (AQL 1.5).

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

**Material of gloves**

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

(Contd. on page 5)

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

Printing date 16.08.2017

Version number 1

Revision: 16.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 1

(Contd. of page 4)

Product quality must comply with standard EN 374.

**Penetration time of glove material** Breakthrough time: > 120 min.**For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

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

Nitrile rubber, NBR

Natural rubber, NR

Thickness: 0.11 mm.

**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:

|                         |                 |
|-------------------------|-----------------|
| <b>Form:</b>            | liquid          |
| <b>Colour:</b>          | Colourless      |
| <b>Smell:</b>           | Alcoholoc.      |
| <b>Odour threshold:</b> | Not determined. |

|                           |     |
|---------------------------|-----|
| <b>pH-value at 20 °C:</b> | 7.5 |
|---------------------------|-----|

##### Change in condition

|                                      |          |
|--------------------------------------|----------|
| <b>Melting point/freezing point:</b> | Ca. 0 °C |
|--------------------------------------|----------|

|  |                                 |
|--|---------------------------------|
| <b>Flash point:</b>                            | 27 °C                           |
| <b>Inflammability (solid, gaseous)</b>         | Not applicable.                 |
| <b>Ignition temperature:</b>                   | 455 °C                          |
| <b>Decomposition temperature:</b>              | Not determined.                 |
| <b>Self-inflammability:</b>                    | Not self-inflammable.           |
| <b>Explosive properties:</b>                   | Heating may cause an explosion. |
| <b>Critical values for explosion:</b>          |                                 |
| <b>Lower:</b>                                  | 5.5 Vol %                       |
| <b>Upper:</b>                                  | 44.0 Vol %                      |
| <b>Steam pressure at 20 °C:</b>                | 128 hPa                         |
| <b>Density at 20 °C</b>                        | 0.88268 g/cm <sup>3</sup>       |
| <b>Relative density</b>                        | No information available.       |
| <b>Vapour density</b>                          | No information available.       |
| <b>Evaporation rate</b>                        | No information available.       |
| <b>Solubility in / Miscibility with</b>        |                                 |
| <b>Water:</b>                                  | Fully miscible.                 |
| <b>Partition coefficient: n-octanol/water:</b> | No information available.       |
| <b>Viscosity:</b>                              |                                 |
| <b>dynamic:</b>                                | No information available.       |
| <b>kinematic:</b>                              | No information available.       |
| <b>Solvent content:</b>                        |                                 |
| <b>Organic solvents:</b>                       | 50.0 %                          |
| <b>Water:</b>                                  | 50.0 %                          |
| <b>Solids content:</b>                         | 0.0 %                           |

(Contd. on page 6)

GB

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

Printing date 16.08.2017

Version number 1

Revision: 16.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 1

(Contd. of page 5)

**9.2 Other information**

No further relevant information available.

**SECTION 10: Stability and reactivity****10.1 Reactivity** No further relevant information available.**10.2 Chemical stability** The product is chemically stable under the indicated storage conditions.**Thermak 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:**

Heat, flames, sparks.

Avoid contact with incompatible materials.

**10.5 Incompatible materials:**

Strong oxidizing agents and inorganic nitrates

Strong acids.

Rubber, various plastics.

Alkali and alkaline earth metals.

**10.6 Hazardous decomposition products:** In case of burning of larger amounts: See Section 5.**SECTION 11: Toxicological information****11.1 Information on toxicological effects****Acute toxicity** Based on available data, the classification criteria are not met.**LD/LC50 values that are relevant for classification:****67-56-1 Methanol**

|            |          |                   |
|------------|----------|-------------------|
| Oral       | LD50     | 5630 mg/kg (rat)  |
| Dermal     | LD50     | 15800 mg/kg (rab) |
| Inhalative | LC50/4 h | 131.25 mg/l (rat) |

**Specific symptoms in biological assay:** No further relevant information available.**Primary irritant effect:****Skin corrosion/irritation** Based on available data, the classification criteria are not met.**Serious eye damage/irritation** Based on available data, the classification criteria are not met.**after swallowing:** Nausea, vomiting.**after inhalation:** 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:** Danger by skin resorption.**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 (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**

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

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

GB

(Contd. on page 7)



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

Printing date 16.08.2017

Version number 1

Revision: 16.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 1

(Contd. of page 6)

### SECTION 12: Ecological information

**12.1 Toxicity****Aquatic toxicity:** No further relevant information available.**12.2 Persistence and degradability** According to OECD criteria readily biodegradable.**12.3 Bioaccumulative potential** Bioaccumulation is not to be expected.**12.4 Mobility in soil** Mobility in soil due to the liquid status.**Additional ecological information:****General notes:** Void.**12.5 Results of PBT and vPvB assessment****PBT:** Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.**vPvB:** Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.**12.6 Other adverse effects** No relevant information available.

### SECTION 13: Disposal considerations

**13.1 Waste treatment methods**

Product residues have to 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.

### SECTION 14: Transport information

**14.1 UN-Number**  
ADR, IMDG, IATA

UN1993

**14.2 UN proper shipping name**  
ADR

1993 FLAMMABLE LIQUID, N.O.S. (METHANOL), (not viscous)

IMDG, IATA

FLAMMABLE LIQUID, N.O.S. (METHANOL)

**14.3 Transport hazard class(es)**

ADR

Class  
Label3 (F1) Flammable liquids.  
3

IMDG, IATA

Class  
Label3 Flammable liquids.  
3**14.4 Packing group**  
ADR, IMDG, IATA

III

**14.5 Environmental hazards:**

Not applicable.

**14.6 Special precautions for user**  
Kemler Number:Warning: Flammable liquids.  
30

(Contd. on page 8)

GB



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

Printing date 16.08.2017

Version number 1

Revision: 16.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 1

(Contd. of page 7)

|  |   |
|--|---|
| <b>EMS Number:</b>   | F-E, S-E  |
| <b>Stowage Category</b>  | A   |
| <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable.   |
| <b>Transport/Additional information:</b>                                       | 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.<br><b>THESE TRANSPORT REGULATIONS APPLY TO THE WHOLE PACKAGE!</b> |
| <b>ADR</b>   |   |
| <b>Limited quantities (LQ)</b>   | 5L  |
| <b>Excepted quantities (EQ)</b>  | Code: E1<br>Maximum net quantity per inner packaging: 30 ml<br>Maximum net quantity per outer packaging: 1000 ml  |
| <b>Transport category</b>  | 3   |
| <b>Tunnel restriction code</b>   | D/E   |
| <b>IMDG</b>  |   |
| <b>Limited quantities (LQ)</b>   | 5L  |
| <b>Excepted quantities (EQ)</b>  | Code: E1<br>Maximum net quantity per inner packaging: 30 ml<br>Maximum net quantity per outer packaging: 1000 ml  |
| <b>UN "Model Regulation":</b>  | UN 1993 FLAMMABLE LIQUID, N.O.S. (NOT VISCOUS) (METHANOL), 3, III   |

### SECTION 15: Regulatory information

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

**Labelling according to Regulation (EC) No 1272/2008** See Section 2.

**Hazard pictograms** See Section 2.

**Signal word** See Section 2.

**Hazard-determining components of labelling:** See Section 2.

**Hazard statements** See Section 2.

**Precautionary statements** See Section 2.

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

#### Directive 2012/18/EU

**Named dangerous substances - ANNEX I** Methanol

#### Seveso category

H3 STOT SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE

P5c FLAMMABLE LIQUIDS

**Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t

**Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t

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

#### National regulations

#### Information about limitation of use:

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

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

| Class | Share in % |
|-------|------------|
| I     | 50.0       |

**Water hazard class:** Void.

(Contd. on page 9)

GB

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

Printing date 16.08.2017

Version number 1

Revision: 16.08.2017

**Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 1**

(Contd. of page 8)

**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

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

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

**Department issuing data specification sheet:** Product Safety

**Contact:** productsafety@medac.de

**Replaces version from:** -

#### Abbreviations and acronyms:

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 3: Acute toxicity – Category 3

STOT SE 1: Specific target organ toxicity (single exposure) – Category 1

GB

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

Printing date 30.08.2017

Version number 1

Revision: 18.08.2017

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** Perma Green™/AP, Perma Green™ Plus/AP Component 2**Article number:** K059B Comp2**Registration number**

This product is a mixture (see chapter 3). Registration number(s) is/are not available for this substance/these substances as the substance(s) or its/their use are exempted from registration according to Article 2 REACH Regulation (EC) No. 1907/2006, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Relevant identified uses:

For in vitro diagnosis.

Uses advised against:

No further relevant information available.

**Sector of Use** SU20 Health services**Product category** PC21 Laboratory chemicals**Process category** PROC15 Use as laboratory reagent**Application of the substance / the mixture** Immunochemical reagent for detection / auxiliary reagent**1.3 Details of the supplier of the safety data sheet****Manufacturer/Distributor:**

Manufacturer:

Diagnostic BioSystems, 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 Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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

Repr. 1B H360D May damage the unborn child.

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

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

**Hazard pictograms**

GHS07 GHS08

**Signal word** Danger

(Contd. on page 2)

GB

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

Printing date 30.08.2017

Version number 1

Revision: 18.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 2

(Contd. of page 1)

**Hazard-determining components of labelling:**

N,N-dimethylformamide

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**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H360D May damage the unborn child.

**Precautionary statements**

P201 Obtain special instructions before use.

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

P280 Wear protective gloves / protective clothing / eye protection

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

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.

H360D May damage the unborn child.

**Precautionary statements**

P201 Obtain special instructions before use.

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

P405 Store locked up.

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

### SECTION 3: Composition/information on ingredients

**3.1. Chemical characterisation: substances** Not applicable. Product is a mixture.**3.2 Chemical characterisation: Mixtures****Description:** Immunochemical reagent / auxiliary reagent**Dangerous components:**

|  |  |            |
|--|--|------------|
| CAS: 68-12-2<br>EINECS: 200-679-5<br>Index number: 616-001-00-X<br>RTECS: LQ 2100000 | N,N-dimethylformamide<br>Flam. Liq. 3, H226<br>Repr. 1B, H360D<br>Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319   | 7-<10%     |
|  | 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)<br>Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331<br>Skin Corr. 1B, H314<br>Aquatic Acute 1, H400; Aquatic Chronic 1, H410<br>Skin Sens. 1, H317 | 0.06-<0.1% |

(Contd. on page 3)

GB

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

Printing date 30.08.2017

Version number 1

Revision: 18.08.2017

**Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 2**

(Contd. of page 2)

**SVHC**

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; consult doctor in case of symptoms.**After skin contact**

Remove contaminated clothes.

Instantly wash with copious 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.

Call a doctor immediately.

**After swallowing**

Let rinse out mouth and then drink plenty of water.

Call doctor.

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

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

**Information for doctor**

Show Safety Data Sheet.

Treatment according to symptoms.

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

No further relevant information available.

**SECTION 5: Firefighting measures****5.1 Extinguishing media****Suitable extinguishing agents** Product itself does not burn. Use fire fighting measures that suit the environment.**For safety reasons unsuitable extinguishing agents** For this mixture no limitations of extinguishing agents are given.**5.2 Special hazards arising from the substance or mixture**

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

In the event of fire may develop:

Carbon monoxide (CO)

Carbon dioxide (CO<sub>2</sub>)Nitrogen oxides (NO<sub>x</sub>)**5.3 Advice for firefighters****Protective equipment:**

In case of burning of a larger amount:

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

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

**Additional information**

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

**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Advice for non-emergency personnel:

Avoid reagent contact with eyes and skin.

Provide sufficient ventilation.

(Contd. on page 4)

GB

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

Printing date 30.08.2017

Version number 1

Revision: 18.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 2

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

(Contd. of page 3)

**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).

Ensure adequate ventilation.

Dispose of the material collected according to respective national regulations.

Afterwards clean with water and cleansing agent.

**6.4 Reference to other sections**

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

### SECTION 7: Handling and storage

**7.1 Precautions for safe handling** Open and handle container with care.**Information about protection against explosions and fires:** No special measures required.**7.2 Conditions for safe storage, including any incompatibilities** No further relevant information available.**Storage****Requirements to be met by storerooms and containers:**

Store container tightly closed.

Store at +2 °C to +8 °C.

**Information about storage in one common storage facility:** Not required.**Further information about storage conditions:**

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

**Storage class**

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:****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.**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**

Do not inhale aerosols.

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

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

Avoid contact with the eyes and skin.

Do not eat or drink while working.

Remove contaminated clothing immediately.

(Contd. on page 5)

—GB—

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

Printing date 30.08.2017

Version number 1

Revision: 18.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 2

(Contd. of page 4)

**Breathing equipment:**

Essential if vapours/aerosols develop.

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

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

**Protection of hands:**

Protective gloves (AQL 1.5).

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

**Material of gloves**

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

The product quality has to comply with DIN EN 455.

**Penetration time of glove material** Penetration time > 120 min.**For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

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

Nitrile rubber, NBR

Natural rubber, NR

Thickness: 0.11 mm.

Penetration time &gt; 120 min.

**Eye protection:** Safety glasses (standard EN 166).**Body protection:** Protective work clothing.**Limitation and supervision of exposure into the environment** Do not empty into drains.**Risk management measures** Void.

## SECTION 9: Physical and chemical properties

**9.1 Information on basic physical and chemical properties****General Information****Appearance:****Form:**

liquid

**Colour:**

No information available.

**Smell:**

slightly amine-like

**Odour threshold:**

No information available.

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

No further relevant information available.

**pH-value:**

No information available.

**Change in condition**

Not applicable.

**Melting point/freezing point:**

Ca. 0 °C

**Initial boiling point and boiling range:**

100 °C

Ca. 100 °C

**Flash point:**

Not applicable.

**Inflammability (solid, gaseous)**

Not applicable.

**Ignition temperature:**

440 °C

**Decomposition temperature:**

No information available.

**Self-inflammability:**

Not self-inflammable.

**Explosive properties:**

Not explosive.

(Contd. on page 6)

GB



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

Printing date 30.08.2017

Version number 1

Revision: 18.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 2

(Contd. of page 5)

**Critical values for explosion:**

|  |                           |
|--|---------------------------|
| <b>Lower:</b>                                  | Not applicable.           |
| <b>Upper:</b>                                  | Not applicable.           |
| <b>Oxidising properties</b>                    | Not applicable.           |
| <b>Steam pressure:</b>                         | No information available. |
| <b>Density</b>                                 | No information available. |
| <b>Relative density</b>                        | No information available. |
| <b>Vapour density</b>                          | No information available. |
| <b>Evaporation rate</b>                        | No information available. |
| <b>Solubility in / Miscibility with</b>        |                           |
| <b>Water:</b>                                  | Miscible                  |
| <b>Partition coefficient: n-octanol/water:</b> | No information available. |
| <b>Viscosity:</b>                              |                           |
| <b>dynamic:</b>                                | No information available. |
| <b>kinematic:</b>                              | No information available. |
| <b>Solvent content:</b>                        |                           |
| <b>Organic solvents:</b>                       | 0.0 %                     |
| <b>Solids content:</b>                         | 10.0 %                    |

9.2 Other information No further relevant information available.

### SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

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

**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: No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

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

**Additional information:** No further relevant information available.

### SECTION 11: Toxicological information

**11.1 Information on toxicological effects****Acute toxicity** Based on available data, the classification criteria are not met.**LD/LC50 values that are relevant for classification:****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)     |

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

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

**Specific symptoms in biological assay:** No further relevant information available.**Primary irritant effect:****Skin corrosion/irritation**

Causes skin irritation.

**Serious eye damage/irritation**

Causes serious eye irritation.

(Contd. on page 7)

GB

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

Printing date 30.08.2017

Version number 1

Revision: 18.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 2

(Contd. of page 6)

**after swallowing:** Mucosal irritations in mouth, pharynx and oesophagus possible.**after inhalation:** Irritations possible.**Respiratory or skin sensitisation**

May cause an allergic skin reaction.

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

May damage the unborn child.

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

### SECTION 12: Ecological information

**12.1 Toxicity****Aquatic toxicity:** No further relevant information available.**12.2 Persistence and degradability** No further relevant information available.**Other information:** No further relevant information available.**Behaviour in environmental systems:****Components:** No relevant information available.**12.3 Bioaccumulative potential** No relevant information available.**12.4 Mobility in soil** Mobility in soil due to the liquid status.**Additional ecological information:****General notes:** Void.**12.5 Results of PBT and vPvB assessment****PBT:** Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.**vPvB:** Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.**12.6 Other adverse effects** No relevant information available.

### SECTION 13: Disposal considerations

**13.1 Waste treatment methods**

Product residues have to 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

-

(Contd. on page 8)

GB

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

Printing date 30.08.2017

Version number 1

Revision: 18.08.2017

Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 2

(Contd. of page 7)

### 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

Stowage Code

Not applicable.

Segregation Code

SW2 Clear of living quarters.

SG35 Stow "separated from" acids.

### 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, 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

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

Not applicable.

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 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

(Contd. on page 9)

GB

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

Printing date 30.08.2017

Version number 1

Revision: 18.08.2017

**Trade name: Perma Green™/AP, Perma Green™ Plus/AP Component 2**

(Contd. of page 8)

contact with the above product.

### Relevant phrases

H226 Flammable liquid and vapour.  
 H301 Toxic if swallowed.  
 H311 Toxic in contact with skin.  
 H312 Harmful in contact with skin.  
 H314 Causes severe skin burns and eye damage.  
 H317 May cause an allergic skin reaction.  
 H319 Causes serious eye irritation.  
 H331 Toxic if inhaled.  
 H332 Harmful if inhaled.  
 H360D May damage the unborn child.  
 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:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 4: Acute toxicity – Category 4

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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 1B: Reproductive toxicity – Category 1B

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

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

GB