

Information about Compilation of Safety Data Sheets

Product: PermaYellow/HRP, Ready To Use 30 ml
Company: Diagnostic BioSystems, Inc.
Article number: K060

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 PermaYellow/HRP Chromogen (Component 1, article number: K 060C), a Safety Data Sheet had been compiled (enclosure).
For the other kit component PermaYellow/HRP Substrate Buffer (Component 2, article number: K 060B), 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

medac

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

Printing date 15.08.2017

Version number 1

Revision: 14.08.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** PermaYellow™/HRP Component 1**Article number:** K060C Comp1**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

Relevant identified uses:

For in vitro diagnosis.

Uses advised against:

No further relevant information available.

Sector of Use SU20 Health services**Product category** PC21 Laboratory chemicals**Process category** PROC15 Use as laboratory reagent**Application of the substance / the mixture**

Immunochemical reagent for detection / auxiliary reagent for in-vitro diagnosis.

1.3 Details of the supplier of the safety data sheet**Manufacturer/Distributor:**

Manufacturer:

Diagnostic BioSystems, Inc.

6616 Owens Drive

Pleasanton, CA 94588, USA

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**

Carc. 2 H351 Suspected of causing cancer.

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

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

Hazard pictograms

GHS08

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

3,3'-Diaminobenzidintetrahydrochlorid

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Hazard statements

H351 Suspected of causing cancer.

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.

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

GHS08

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

3,3'-Diaminobenzidintetrahydrochlorid

Hazard statements

H351 Suspected of causing cancer.

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: 7411-49-6 EINECS: 231-018-9 Index number: 029-215-99-0	3,3'-Diaminobenzidintetrahydrochlorid Carc. 2, H351 Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	3-5%
CAS: 68-12-2 EINECS: 200-679-5 Index number: 616-001-00-X RTECS: LQ 2100000	N,N-dimethylformamide Flam. Liq. 3, H226 Repr. 1B, H360D Acute Tox. 4, H312; Acute Tox. 4, H332; Eye Irrit. 2, H319	0.1-<0.3%

Additional information For the wording of the listed H- and R-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.

Wash with copious amounts of water.

In case of symptoms call a physician.

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After eye contact

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

In case of onset of symptoms consult doctor.

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

Formation of toxic gases is possible during heating or in case of fire.

In the event of fire may develop:

Nitrogen oxides (NO_x)

Hydrogen chloride (HCl)

Carbon dioxide (CO₂)

Carbon monoxide (CO)

5.3 Advice for firefighters**Protective equipment:**

In case of burning of a larger amount:

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.

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.

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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 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 ³ , 10 ppm
	Long-term value: 15 mg/m ³ , 5 ppm
Sk	

DNELs No further relevant information available.**PNECs** No further relevant information available.

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:**

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.

Product quality must comply with standard EN 374.

Penetration time of glove material Breakthrough time: > 120 min.

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

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

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

Nitrile rubber, NBR

Natural rubber, NR

Thickness: 0.11 mm.

Penetration time > 120 min.

Eye protection: Safety glasses (standard EN 166).

Body protection: Protective work clothing.

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

Risk management measures Void.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and 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 at 20 °C: 7.5

Change in condition: Not applicable.

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: No information available.

Decomposition temperature: No information available.

Self-inflammability: Not self-inflammable.

Explosive properties: Not explosive.

Critical values for explosion:

Lower: Not applicable.

Upper: Not applicable.

Oxidising properties: No information available.

Steam pressure at 20 °C: 23 hPa

Density at 20 °C: ca. 1.00 g/cm³

Relative density: No information available.

Vapour density: No information available.

Evaporation rate: No information available.

Solubility in / Miscibility with

Water: Miscible

Partition coefficient: n-octanol/water: Not determined.

Viscosity:

dynamic: No information available.

kinematic: No information available.

Solvent content:

Organic solvents: < 0.2 %

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Water: > 90 %
Solids content: < 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.

Thermal decomposition / conditions to be avoided: No decomposition if used and stored according to specifications.

10.3 Possibility of hazardous reactions

Dangerous reactions are not to be expected handling product according to its intended use.

10.4 Conditions to avoid:

Light.
 Heating.
 Moisture.

10.5 Incompatible materials: Oxidising materials.

10.6 Hazardous decomposition products:

Under correct conditions of storage and use, hazardous decomposition products should not be produced.

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:

Oral	LD50	2800 mg/kg (mouse)
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Specific symptoms in biological assay: No further relevant information available.

Primary irritant effect:

Skin corrosion/irritation Irritations possible.

Serious eye damage/irritation Based on available data, the classification criteria are not met.

after swallowing: Mucosal irritations in mouth, pharynx and oesophagus possible.

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: Danger of cutaneous absorption.

Additional toxicological information: No further relevant information available.

Toxicokinetics, metabolism and distribution No relevant information available.

Acute effects (acute toxicity, irritation and corrosivity) No acute toxicity information available for this product.

Sensitisation No sensitising effect known.

Repeated dose toxicity Hepatopathy.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity

Suspected of causing cancer.

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.

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SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

Other information: No further relevant information available.

Behaviour in environmental systems:

Components: No relevant information available.

12.3 Bioaccumulative potential No relevant information available.

12.4 Mobility in soil Mobility in soil due to the liquid status.

Ecotoxicological effects:

Remark: No further relevant information available.

Additional ecological information:

General notes: Void.

12.5 Results of PBT and vPvB assessment

PBT: PBT assessment not available as chemical safety assessment not required/not conducted.

vPvB: vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects No relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product residues have to be disposed of according to the Waste Framework Directive as well as national and regional regulations in each 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

Hazard pictograms See Section 2.

Signal word See Section 2.

Hazard-determining components of labelling: See Section 2.

Hazard statements See Section 2.

Precautionary statements See Section 2.

Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 9d

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

75-12-7 formamide

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

H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

H360D May damage the unborn child.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de

Replaces version from: -

Abbreviations and acronyms:

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

ICAO: International Civil Aviation Organisation

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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

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LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 3: Flammable liquids – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Carc. 2: Carcinogenicity – Category 2
Repr. 1B: Reproductive toxicity – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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