

Information about Compilation of Safety Data Sheets

Product: Mouse/Rabbit PolyVue™ HP/DAB Detection System
Manufacturer: Diagnostic BioSystems
6610 Owens Drive
Pleasanton, CA 94588, USA
Article numbers: PVP25D, PVP100D, PVP250D, PVP1000D

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 Tissue Primer (Component 1) and Stable DAB/Plus (Component 3) Safety Data Sheets have been compiled (enclosure).

For the remaining kit component Background Blocker (Component 2), no Safety Data Sheet is required after classifications 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: September 2022

medac

Product Safety
Health, Safety & Environment (HSE)
Phone: +49 4103 8006-0
Fax: +49 4103 8006-100
E-mail: productsafety@medac.de

Theaterstrasse 6
22880 Wedel
Germany

Attachment

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** DiagBioSyst PolyVue Plus HRP/DAB Detection System - Tissue Primer**Article number:** PVP25D A, PVP100D A, PVP250D A, PVP1000D A**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 UK REACH Regulation (EC) No. 1907/2006, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.

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

Relevant identified uses:

For in vitro diagnosis.

Uses advised against:

For Research Use.

Sector of Use SU20 Health services**Application of the substance / the mixture** Immunochemical reagent for detection / auxiliary reagent**1.3 Details of the supplier of the safety data sheet****Manufacturer/Distributor:**

Manufacturer:

Diagnostic BioSystems

6616 Owens Drive

Pleasanton, CA 94588, USA

phone: +1 925 484-3350

Distributor:

medac GmbH

Theaterstrasse 6

22880 Wedel, Germany

phone: +49 4103 8006-0

Informing department:

Product Safety

productsafety@medac.de

1.4 Emergency telephone number:

Giftinformationszentrum-Nord, phone: +49 551 19 240 (service in German and English, 24 hours permanently accessible).

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

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

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

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

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

The product is classified according to Regulation (EC) No 1272/2008 (GHS/GB 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.

(Contd. on page 2)

-GB-

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Tissue Primer

(Contd. of page 1)

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

P280 Wear protective gloves.

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

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

Additional information:

Product contains: Reportable explosives precursors. Making available, introduction, possession and use according to Regulation (EU) 2019/1148, Article 9.

2.3 Other hazards Void.**Results of PBT and vPvB assessment****PBT:** Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.**vPvB:** Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.**SECTION 3: Composition/information on ingredients****3.2 Mixtures****3.1. Chemical characterisation: substances** Not applicable. Product is a mixture.**Description:** Water based solution**Dangerous components:**

CAS: 7722-84-1 EINECS: 231-765-0 Index number: 008-003-00-9	hydrogen peroxide solution <div> <div>Ox. Liq. 1, H271</div> <div>Skin Corr. 1A, H314</div> <div>Acute Tox. 4, H302; Acute Tox. 4, H332</div> </div> <div>Specific concentration limits: Ox. Liq. 1; H271: $C \geq 70 \%$ Ox. Liq. 2; H272: $50 \% \leq C < 70 \%$ Skin Corr. 1A; H314: $C \geq 70 \%$ Skin Corr. 1B; H314: $50 \% \leq C < 70 \%$ Skin Irrit. 2; H315: $35 \% \leq C < 50 \%$ Eye Dam. 1; H318: $C \geq 8 \%$ Eye Irrit. 2; H319: $5 \% \leq C < 8 \%$ STOT SE 3; $C \geq 35 \%$</div>	$\geq 3 - < 5 \%$
CAS: 55965-84-9 Index number: 613-167-00-5	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) <div> <div>Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330</div> <div>Skin Corr. 1C, H314; Eye Dam. 1, H318</div> <div>Aquatic Acute 1, H400 (M=100); Aquatic Chronic 1, H410 (M=100)</div> <div>Skin Sens. 1A, H317</div> </div> <div>Specific concentration limits: Skin Corr. 1C; H314: $C \geq 0.6 \%$ Skin Irrit. 2; H315: $0.06 \% \leq C < 0.6 \%$ Eye Dam. 1; H318: $C \geq 0.6 \%$ Eye Irrit. 2; H319: $0.06 \% \leq C < 0.6 \%$ Skin Sens. 1A; H317: $C \geq 0.0015 \%$</div>	$\geq 0.0025 - < 0.025 \%$

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**

Wash with copious amounts of water.

Remove contaminated clothes.

In case of symptoms call a physician.

(Contd. on page 3)

GB

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Tissue Primer

(Contd. of page 2)

After eye contact

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

Consult ophthalmologist.

After swallowing In case of disorders consult doctor.

Information for doctor Show Safety Data Sheet.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

Danger No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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

Suitable extinguishing agents Product itself does not burn. Use fire fighting measures that suit the environment.

For safety reasons unsuitable extinguishing agents For this mixture no limitations of extinguishing agents are given.

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

5.3 Advice for firefighters**Protective equipment:**

In case of fire of large quantities:

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/safety glasses.

Additional information

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

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

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

Advice for non-emergency personnel:

Avoid reagent contact with eyes and skin.

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

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

6.3 Methods and material for containment and cleaning up:

Ensure adequate ventilation.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Afterwards clean with water and cleansing agent.

Dispose of contaminated material as waste according to Section 13.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling No special precautions necessary if handled correctly.

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

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

Storage

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

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

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

(Contd. on page 4)

GB

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Tissue Primer

(Contd. of page 3)

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

8.1 Control parameters

Components with critical values that require monitoring at the workplace:**7722-84-1 hydrogen peroxide solution**

WEL	Short-term value: 2.8 mg/m ³ , 2 ppm Long-term value: 1.4 mg/m ³ , 1 ppm
-----	---

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.

Appropriate engineering controls No further data; see Section 7.**Individual protection measures, such as 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.**Hand protection** Disposable medical gloves (AQL 1.5).**Material of gloves**

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

The product quality has to comply with DIN EN 455.

Penetration time of glove material Not applicable.**For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

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

Product has not been designed for permanent contact.

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

Nitrile rubber, NBR

Natural rubber, NR

Thickness: 0.11 mm.

Eye/face protection Safety glasses (standard EN 166).**Body protection:** Protective work clothing.**Environmental exposure controls** Do not empty into drains.**Risk management measures** Void.

GB

(Contd. on page 5)

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Tissue Primer

(Contd. of page 4)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Colour:	colourless
Smell:	odourless
Odour threshold:	No information available.
Melting point/freezing point:	No information available.
Flammability	Not applicable.
Lower and upper explosion limit	
Lower:	Not applicable.
Upper:	Not applicable.
Flash point:	Not applicable.
Ignition temperature:	Not applicable.
Decomposition temperature:	No information available.
pH	No information available.
Viscosity:	
Kinematic viscosity	No information available.
dynamic:	No information available.
Solubility	
Water:	Fully miscible.
Partition coefficient n-octanol/water (log value)	No information available.
Steam pressure:	No information available.
Density and/or relative density	
Density	No information available.
Relative density	No information available.
Vapour density	No information available.

9.2 Other information

Appearance:	
Form:	liquid
Important information on protection of health and environment, and on safety.	
Self-inflammability:	Not self-inflammable.
Explosive properties:	Not explosive.
Solvent content:	
Organic solvents:	<0.1 %
Water:	94.9 %
Solids content:	>0.0 %
Change in condition	
Softening point/range	
Oxidising properties	Not oxidizing.
Evaporation rate	No information available.

Information with regard to physical hazard classes

Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable gases in contact with water	Void
Oxidising liquids	Void

(Contd. on page 6)

GB

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Tissue Primer

(Contd. of page 5)

Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

SECTION 10: Stability and reactivity

10.1 Reactivity For this mixture no relevant information available.

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

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

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid: No further relevant information available.

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

10.6 Hazardous decomposition products:

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

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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.

55965-84-9 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	LD ₅₀	3.5 mg/kg (rat)
Dermal	LD ₅₀	>5,000 mg/kg (rab)
Inhalative	LC ₅₀ /4 h	0.33 mg/l (rat)

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: Slight mucosal irritations in mouth, pharynx and oesophagus possible.

after inhalation: No irritant effects known.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

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.

11.2 Information on other hazards

Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential Bioaccumulation is not to be expected.

(Contd. on page 7)

GB

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Tissue Primer

(Contd. of page 6)

12.4 Mobility in soil No relevant information available.**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 Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.**12.7 Other adverse effects****Additional ecological information:****General notes:**

Water hazard class 2 (Self-assessment): hazardous for water.

Do not allow product to reach ground water, water bodies or sewage system!

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 the latest versions.

Uncleaned packagings:**Recommendation:** Disposal according to the respective national official regulations.**SECTION 14: Transport information****14.1 UN number or ID number**

ADR, ADN, IMDG, IATA not regulated

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA not regulated

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class not regulated

14.4 Packing group

ADR, IMDG, IATA not regulated

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user

Not applicable.

14.7 Maritime transport in bulk according to IMO instruments

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.

UN "Model Regulation":

not regulated

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Labelling according to Regulation (EC) No 1272/2008** See Section 2.**Hazard pictograms** Not applicable.**Signal word** Not applicable.**Hazard-determining components of labelling:** Not applicable.**Hazard statements** Not applicable.**Precautionary statements** Not applicable.

(Contd. on page 8)

GB

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Tissue Primer

(Contd. of page 7)

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.

National regulations
Information about limitation of use:

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

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

Water hazard class: Water hazard class 2 (Self-assessment): hazardous for water.

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 GmbH shall not be held liable for any damage resulting from handling or from contact with the above product.

Relevant phrases

H271 May cause fire or explosion; strong oxidiser.
 H301 Toxic if swallowed.
 H302 Harmful if swallowed.
 H310 Fatal in contact with skin.
 H314 Causes severe skin burns and eye damage.
 H317 May cause an allergic skin reaction.
 H318 Causes serious eye damage.
 H330 Fatal if inhaled.
 H332 Harmful if inhaled.
 H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.

Department issuing data specification sheet: Product Safety

Contact: productsafety@medac.de

Replaces version from: -

Abbreviations and acronyms:

ADR: Accord relatif au transport international 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 (UK REACH)
 PNEC: Predicted No-Effect Concentration (UK REACH)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 Ox. Liq. 1: Oxidizing liquids – Category 1
 Acute Tox. 3: Acute toxicity – Category 3
 Acute Tox. 4: Acute toxicity – Category 4
 Acute Tox. 2: Acute toxicity – Category 2
 Skin Corr. 1A: Skin corrosion/irritation – Category 1A
 Skin Corr. 1C: Skin corrosion/irritation – Category 1C
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1
 Skin Sens. 1: Skin sensitisation – Category 1
 Skin Sens. 1A: Skin sensitisation – Category 1A
 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
 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** DiagBioSyst PolyVue Plus HRP/DAB Detection System - Stable DAB/Plus**Article number:** PVP25D C, PVP100D C, PVP250D C, PVP1000D C**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 UK 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**Environmental release category** ERC12c Use of articles at industrial sites with low release**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

6616 Owens Drive

Pleasanton, CA 94588, USA

phone: +1 925 484-3350

Distributor:

medac GmbH

Theaterstrasse 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**

Muta. 2 H341 Suspected of causing genetic defects.

Carc. 1A H350 May cause cancer.

Repr. 1B H360D May damage the unborn child.

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

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

Hazard pictograms

GHS08

Signal word Danger

(Contd. on page 2)

GB

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Stable DAB/Plus

(Contd. of page 1)

Hazard-determining components of labelling:3,3'-Diaminobenzidin-tetrahydrochlorid Hydrat
imidazole**Hazard statements**

H341 Suspected of causing genetic defects.

H350 May cause cancer.

H360D May damage the unborn child.

Precautionary statements

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

P280 Wear protective gloves / protective clothing / eye protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

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

CAS: 868272-85-9 EINECS: 231-018-9	3,3'-Diaminobenzidin-tetrahydrochlorid Hydrat	≥1-≤5%
	<div> <div></div> <div>Muta. 2, H341; Carc. 1A, H350</div> </div> <div> <div></div> <div>Acute Tox. 4, H302; Eye Irrit. 2, H319</div> </div>	
CAS: 288-32-4 EINECS: 206-019-2 Index number: 613-319-00-0 RTECS: NI 3325000	imidazole	≥0.3-<0.5%
	<div> <div></div> <div>Repr. 1B, H360D</div> </div> <div> <div></div> <div>Skin Corr. 1C, H314</div> </div>	
	<div> <div></div> <div>Acute Tox. 4, H302</div> </div>	

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

Wash with copious amounts of water.

Remove contaminated clothes.

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.

In case of onset of symptoms consult ophthalmologist.

After swallowing

Wash out mouth with copious amounts of water.

Call doctor.

Information for doctor Show Safety Data Sheet.**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.

(Contd. on page 3)

GB

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Stable DAB/Plus

(Contd. of page 2)

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 is possible.

In the event of fire may develop:

Carbon dioxide (CO₂)

5.3 Advice for firefighters

Protective equipment:

In case of fire of large quantities:

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/safety glasses.

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

Provide sufficient ventilation.

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

Advice for non-emergency personnel:

Avoid reagent contact with eyes and skin.

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.

Afterwards clean with water and cleansing agent.

Dispose of the material collected according to respective national regulations.

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 in cool, properly ventilated location.

Protect from light.

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 Please see the respective national guidelines.

(Contd. on page 4)

GB

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Stable DAB/Plus

(Contd. of page 3)

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

8.1 Control parameters

Components with critical values that require monitoring at the workplace:

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 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.

Appropriate engineering controls No further data; see Section 7.

Individual protection measures, such as 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.

Do not eat or drink while working.

Remove contaminated clothing immediately.

Breathing equipment: Not required.

Hand protection

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 end user 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.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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.

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/face protection Safety glasses (standard EN 166).

Body protection: Protective work clothing.

Environmental exposure controls Do not empty into drains.

Risk management measures Void.

GB

(Contd. on page 5)

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Stable DAB/Plus

(Contd. of page 4)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state	liquid
Colour:	colourless
Smell:	odourless
Odour threshold:	No information available.
Melting point/freezing point:	No information available.
Flammability	Not applicable.
Lower and upper explosion limit	
Lower:	Not applicable.
Upper:	Not applicable.
Flash point:	Not applicable.
Ignition temperature:	No information available.
Decomposition temperature:	No information available.
pH	Not determined.
Viscosity:	
Kinematic viscosity	No information available.
dynamic:	No information available.
Solubility	
Water:	Miscible
Partition coefficient n-octanol/water (log value)	No information available.
Steam pressure:	No information available.
Density and/or relative density	
Density	No information available.
Relative density	No information available.
Vapour density	No information available.

9.2 Other information

Appearance:	
Form:	liquid
Important information on protection of health and environment, and on safety.	No further relevant information available.
Self-inflammability:	No information available.
Explosive properties:	Not explosive.
Solvent content:	
Organic solvents:	0 %
Water:	94.4 %
Solids content:	0 %
Change in condition	Not applicable.
Softening point/range	
Oxidising properties	No information available.
Evaporation rate	No information available.

Information with regard to physical hazard classes

Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable gases in contact with water	Void

(Contd. on page 6)

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Stable DAB/Plus

(Contd. of page 5)

Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

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 the specifications.

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid:

Light.

Heating.

10.5 Incompatible materials:

Oxidising materials.

Strong bases.

Strong acids.

Metals.

10.6 Hazardous decomposition products:

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

Additional information: No further relevant information available.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

LD/LC₅₀ values that are relevant for classification:

288-32-4 imidazole

Oral LD₅₀ 220 mg/kg (rat)

Specific symptoms in biological assay: No further relevant information available.

Skin corrosion/irritation Irritations possible.

Serious eye damage/irritation

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

after inhalation: Irritations possible.

Germ cell mutagenicity Suspected of causing genetic defects.

Carcinogenicity May cause cancer.

Reproductive toxicity May damage the unborn child.

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.

11.2 Information on other hazards

Endocrine disrupting properties

None of the ingredients is listed.

GB

(Contd. on page 7)

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Stable DAB/Plus

(Contd. of page 6)

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 No relevant information available.

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 Endocrine disrupting properties For information on endocrine disrupting properties see section 11.

12.7 Other adverse effects

Remark: No further relevant information available.

Additional ecological information:

General notes:

Water danger class 3 (Self-assessment): extremely hazardous for water.

Do not allow product to reach ground water, water bodies or sewage system, even in small quantities.

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 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 or ID number

ADR, IMDG, IATA not regulated

14.2 UN proper shipping name

ADR, IMDG, IATA not regulated

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class not regulated

14.4 Packing group

ADR, IMDG, IATA not regulated

14.5 Environmental hazards:

Marine pollutant: No

14.6 Special precautions for user

Not applicable.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

(Contd. on page 8)

GB

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Stable DAB/Plus

(Contd. of page 7)

Transport/Additional information:

Not classified as dangerous in the meaning of transport regulations as issued in the latest version.
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.

UN "Model Regulation":

not regulated

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.**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: Water danger class 3 (Self-assessment): extremely hazardous for water.**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 GmbH shall not be held liable for any damage resulting from handling or from contact with the above product.

Relevant phrases

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H319 Causes serious eye irritation.

H341 Suspected of causing genetic defects.

H350 May cause 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 relatif au transport international 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)

(Contd. on page 9)

GB

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

Printing date 20.09.2022

Version number 1

Revision: 20.09.2022

Trade name: DiagBioSyst PolyVue Plus HRP/DAB Detection System - Stable DAB/Plus

(Contd. of page 8)

DNEL: Derived No-Effect Level (UK REACH)
 PNEC: Predicted No-Effect Concentration (UK REACH)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 Acute Tox. 4: Acute toxicity – Category 4
 Skin Corr. 1C: Skin corrosion/irritation – Category 1C
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 Muta. 2: Germ cell mutagenicity – Category 2
 Carc. 1A: Carcinogenicity – Category 1A
 Repr. 1B: Reproductive toxicity – Category 1B

GB