

Safety Data Sheet PolyVue Plus HRP/DAB Detection System (OSHA)

SECTION 1: Identification

1.1 GHS Product identifier

Product name PolyVue Plus HRP/DAB Detection System

Product number PVP25D, PVP100D, PVP250D, PVP1000D PolyVue Plus HRP/DAB Detection System

1.2 Other means of identification

Component 1. K054: Tissue Primer Component 2. K023: Background Blocker Component 3. K047: Stable DAB/Plus

1.3 Recommended use of the chemical and restrictions on use

In Vitro Diagnostic Use

1.4 Supplier's details

Name Diagnostic Biosystems
Address 6616 Owens Drive
Pleasanton CA 94588

USA

Telephone (888) 896-3350

email customersupport@dbiosys.com

1.5 Emergency phone number

(925) 484-3350 (9AM-6PM, Monday - Friday, Pacific Standard Time)

SECTION 2: Hazard identification

2.1 Classification of the substance or mixture

GHS classification in accordance with: OSHA (29 CFR 1910.1200)

- Acute toxicity, inhalation (chapter 3.1), Cat. 5
- Acute toxicity, oral (chapter 3.1), Cat. 5
- Carcinogenicity (C.4.9), Cat. 1B
- Germ cell mutagenicity (C.4.8), Cat. 2
- Eye damage/irritation (C.4.5), Cat. 1

- Skin corrosion/irritation (C.4.4), Cat. 1A
- Toxic to reproduction (C.4.10), Cat. 1B

2.2 GHS label elements, including precautionary statements

Pictogram



1. Exclamation mark; 2. Health hazard; 3. Corrosion

Signal word	Danger

Hazard statement(s)

H314 Causes severe skin burns and eye damage

H317 May cause an allergic skin reaction

H318 Causes serious eye damage

H332 Harmful if inhaled

H341 Suspected of causing genetic defects

H350 May cause cancer

H360 May damage fertility or the unborn child

Precautionary statement(s)

P201 Obtain special instructions before use.

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

P260 Do not breathe dust/fume/gas/mist/vapors/spray.
P261 Avoid breathing dust/fume/gas/mist/vapors/spray.

P264 Wash hands thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse

skin with water/shower.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses if present and easy to do. Continue rinsing.

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

P310 Immediately call a POISON CENTER/doctor.
P312 Call a POISON CENTER/doctor if you feel unwell.

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

Take off contaminated clothing and wash it before reuse.

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

P501 Dispose of contents/container to a licensed disposal company.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Component 1.

1. Reaction mass of: 5-Chloro-2-methyl4- isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)

Concentration < 0.1 % (volume)

Other names / synonyms 3(2H)-Isothiazolone, 5-chloro-2-methyl-, mixt. with 2-methyl-3(2H)-

isothiazolone; Kathon 886;

EC no.

CAS no. 55965-84-9 Index no. 613-167-00-5

Acute toxicity, inhalation (C.4.3), Cat. 2
Acute toxicity, dermal (C.4.2), Cat. 2
Acute toxicity, oral (C.4.1), Cat. 3

- Skin corrosion/irritation (C.4.4), Cat. 1C
- Eye damage/irritation (C.4.5), Cat. 1 Sensitization, skin (C.4.7), Cat. 1A
- Hazardous to the aquatic environment, short-term (acute) (chapter 4.1), Cat. 1

- Hazardous to the aquatic environment, long-term (chronic) (chapter 4.1), Cat. 1

H301 Toxic 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

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

SCLs/M-factors/ATEs Skin Corr. 1C; : $C \ge 6\%$

Skin Irrit. 2; H315: ,06 % ≤ C < ,6 %

Eye Dam. 1; : C ≥ ,6 %

Eye Irrit. 2; H319: $,06 \% \le C < ,6 \%$ Skin Sens. 1A; : $C \ge ,0015 \%$

M=100 M=100

2. Hydrogen peroxide

Concentration < 5 % (volume)

Other names / synonyms ALBONE; DIHYDROGEN DIOXIDE; HYDROGEN DIOXIDE; HYDROGEN

PEROXIDE; Hydrogen peroxide (H2O2); hydrogen peroxide solution;

hydrogen peroxide solution; HYDROGEN PEROXIDE SOLUTION; Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide; Hydrogenii peroxidum; HYDROGENPEROXIDE; HYDROPEROXIDE; PEROXIDE; SUPEROXOL;

T-STUFF

EC no. 231-765-0 CAS no. 7722-84-1 Index no. 008-003-00-9

- Acute toxicity, inhalation (C.4.3), Cat. 4

- Acute toxicity, oral (C.4.1), Cat. 4 - Oxidizing liquids (C.4.26), Cat. 1

- Skin corrosion/irritation (C.4.4), Cat. 1A

H271 May cause fire or explosion; strong oxidizer

H302 Harmful if swallowed

H314 Causes severe skin burns and eye damage

H332 Harmful if inhaled

SCLs/M-factors/ATEs Ox. Lig. 1; H271: C ≥ 70 %****

Ox. Liq. 2; H272: 50 % \leq C < 70 % ****

*

Skin Corr. 1A; H314: C ≥ 70 % Skin Corr. 1B; H314: 50 % ≤ C < 70 % Skin Irrit. 2; H315: 35 % ≤ C < 50 % Eye Dam. 1; H318: 8 % ≤ C < 50 % Eye Irrit. 2; H319: 5 % ≤ C < 8 % STOT SE 3; H335; C ≥ 35 %

3. Hydrochloric acid

Concentration < 0.05 % (volume)

Other names / synonyms Acidum hydrochloricum; HYDROCHLORIC ACID; Hydrogen chloride

EC no. 231-595-7 CAS no. 7647-01-0 Index no. 017-002-01-X

- Specific target organ toxicity (single exposure) (C.4.11), Cat. 3

- Skin corrosion/irritation (C.4.4), Cat. 1B

H314 Causes severe skin burns and eye damage

H335 May cause respiratory irritation SCLs/M-factors/ATEs Skin Corr. 1B; H314: $C \ge 25 \%$

Skin Irrit. 2; H315: 10 % \leq C < 25 % Eye Irrit. 2; H319: 10 % \leq C < 25 % STOT SE 3; H335: C \geq 10 %

Component 2.
1. SODIUM AZIDE

Concentration < 0.1 % (weight)

Other names / synonyms Sodium azide (Na(N3))

EC no. 247-852-1 CAS no. 26628-22-8 Index no. 011-004-00-7

- Acute toxicity, dermal (C.4.2), Cat. 1

- Acute toxicity, inhalation (C.4.3), Cat. 2

- Acute toxicity, oral (C.4.1), Cat. 2

- Specific target organ toxicity (repeated exposure) (C.4.12), Cat. 2

- Hazardous to the aquatic environment, short-term (acute) (chapter 4.1), Cat. 1

- Hazardous to the aquatic environment, long-term (chronic) (chapter 4.1), Cat. 1

Component 3.

1. 3,3'-Diaminobenzidine tetrahydrochloride hydrate

Concentration 1 - 5 % (weight)

Other names / synonyms [1,1'-Biphenyl]-3,3',4,4'-tetramine: biphenyl-3,3',4,4'-tetrayltetraamine;

diaminobenzidine tetrahydrochloride hydrate

EC no. 231-018-9 CAS no. 868272-85-9

- Serious eye damage/eye irritation (chapter 3.3), Cat. 2

Acute toxicity, oral (C.4.1), Cat. 4
Carcinogenicity (C.4.9), Cat. 1B
Germ cell mutagenicity (C.4.8), Cat. 2

H341 Suspected of causing genetic defects

H350 May cause cancer

6. Imidazole

Concentration 0.1 - 0.5 % (weight)

Other names / synonyms 1H-Imidazole; EC no. 206-019-2 CAS no. 288-32-4 Index no. 613-319-00-0

Toxic to reproduction (C.4.10), Cat. 1B
Acute toxicity, oral (C.4.1), Cat. 4
Skin corrosion/irritation (C.4.4), Cat. 1C

H302 Harmful if swallowed

H314 Causes severe skin burns and eye damage

H360D May damage the unborn child

7. Polysorbate 21

Concentration < 0.15 % (volume)

Other names / synonyms Polyoxyethylene sorbitan monolaurate; Polysorbate 20; Sorbitan,

monododecanoate, poly(oxy-1,2-ethanediyl) derivs; Sorbitan,

monododecanoate, poly(oxy-1,2-ethanediyl) derivs.; Tween 20

EC no. 500-018-3 CAS no. 9005-64-5

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

General advice Consult a physician. Show this safety data sheet to the doctor in attendance.

If breathed in, move person into fresh air. If not breathing, give artificial

respiration.

Do NOT induce vomiting. Never give anything by mouth to an unconscious

person. Rinse mouth with water. Consult a physician.

In case of skin contact Rinse with plenty of water. Get medical attention if irritation develops and

persists.

In case of eye contact Rinse thoroughly with plenty of water for at least 15 minutes. Get medical

attention if symptoms occur.

If swallowed Call a poison center or doctor if you feel unwell. If vomiting occurs naturally,

> have victim lean forward to reduce the risk of aspiration. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything

by mouth to an unconscious person.

Acute and delayed symptoms and effects: May cause gastrointestinal irritation. Signs/symptoms may include abdominal pain, stomach upset,

nausea, vomiting and diarrhea.

Personal protective equipment for first-aid responders

Ensure adequate ventilation. Use personal protective equipment. For

personal protection see section 8.

Most important symptoms/effects, acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section

4.3 Indication of immediate medical attention and special treatment needed, if necessary

No data available

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Use extinguishing media appropriate for surrounding fire.

5.2 Specific hazards arising from the chemical

Reaction mass of: 5-Chloro-2-methyl4- isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1): Carbon oxide.

Nitrogen oxides.

SODIUM AZIDE: Sodium oxides

3,3'-Diaminobenzidine: Carbon oxides, Nitrogen oxides (NOx)

Special protective actions for fire-fighters 5.3

Wear self-contained breathing apparatus for firefighting if necessary.

Further information

No data available.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

Ensure adequate ventilation. Use personal protective equipment. For personal protection see section 8.

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas. For personal protection see section 8.

6.2 Environmental precautions

Should not be released into the environment. See Section 12 for additional ecological information.

6.3 Methods and materials for containment and cleaning up

Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).

Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

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

CAS: 26628-22-8 (EC: 247-852-1)

Sodium azide

ACGIH: 0.29 mg/m3 (C); 0.1 ppm (C) hydrazoic acid vapor TLV® inhalation; NIOSH: 0.29 mg/m3 (C); 0.1 ppm (C) hydrazoic acid vapor REL-C inhalation

CAS: 7647-01-0

Hydrochloric acid

Cal/OSHA: (C) 5 ppm PEL inhalation; NIOSH: (C) 5 ppm REL inhalation; OSHA: (C) 5 ppm PEL inhalation; (C) 7 mg/m3 PEL inhalation

CAS: 7722-84-1

Hydrogen peroxide

ACGIH (USA): 1 ppm TLV® inhalation; Cal/OSHA (USA): 1 ppm PEL inhalation; NIOSH (USA): 1 ppm REL inhalation; OSHA (USA): 1 ppm PEL inhalation; 1.4 mg/m3 PEL inhalation

8.2 Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Pictograms

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Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal hazards

No data available

Control banding approach

No data available.

Environmental exposure controls

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

SECTION 9: Physical and chemical properties and safety characteristics

Physical state Liquid Appearance Clear

Color Varies by Component

Odor Odorless

Odor threshold

No data available.

pH No data available.

Melting point/freezing point No data available.

Boiling point or initial boiling point and boiling range
No data available.
No data available.

Evaporation rate

Flammability

No data available.

No data available.

No data available.

Lower and upper explosion limit/flammability limit

Vapor pressure

No data available.

No data available.

No data available.

Relative vapor density

No data available.

Density and/or relative density

No data available.

Solubility

No data available.

No data available.

Partition coefficient n-octanol/water (log value)

Auto-ignition temperature

No data available.

No data available.

Decomposition temperature

Kinematic viscosity

No data available.

Particle characteristics

No data available.

Supplemental information regarding physical hazard classes

No data available.

Further safety characteristics (supplemental)

No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

None under normal use conditions.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

None under normal use conditions.

10.4 Conditions to avoid

Exposure to moisture.

Avoid storing in direct sunlight and avoid extremes of temperature.

Heat, flames and sparks.

10.5 Incompatible materials

Hydrogen peroxide: Zinc, Powdered metals, Iron, Copper, Nickel, Brass, Iron and iron salts.

3,3'-Diaminobenzidine: Strong oxidizing agents

10.6 Hazardous decomposition products

Other decomposition products - No data available In the event of fire: see section 5

Hydrogen peroxide: Hazardous decomposition products formed under fire conditions. - Nature of decomposition products not known.

SECTION 11: Toxicological information

Information on toxicological effects

Acute toxicity

The ATE (gas inhalation) of the mixture is: 90000 ppmV

The ATE (oral) of the mixture is: 5000 mg/kg bw

3,3'-Diaminobenzidine

LD50 Oral - Mouse - 1,834 mg/kg

Polyoxyethylene sorbitan monolaurate LD50 Oral - Rat - 40,554.0 mg/kg

Sodium azide LD50 Oral - Rat - 27 mg/kg

Skin corrosion/irritation

Sodium azide LD50 Skin - Rat - 20 mg/kg

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitization

Sodium azide

LC50 Inhalation - Rat - 0.054 - 0.52 mg/l - 4 hr

Germ cell mutagenicity

May cause genetic defects.

Carcinogenicity

3,3'-Diaminobenzidine

Oral - Rat

Result: Tumorigenic:Equivocal tumorigenic agent by RTECS criteria. Skin and Appendages: Other: Tumors. Presumed to have carcinogenic potential for humans

Reproductive toxicity

May damage fertility or the unborn child

STOT-single exposure

No data available.

STOT-repeated exposure

No data available.

Aspiration hazard

No data available.

Additional information

No data available.

SECTION 12: Ecological information

Toxicity

Sodium azide

LC50 - Oncorhynchus mykiss (rainbow trout) - 2.96 mg/l - 96 h

Sodium azide

EC50 - Pseudokirchneriella subcapitata (green algae) - 0.348 mg/l - 96 h

Persistence and degradability

No data available.

Bioaccumulative potential

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No data available.

Mobility in soil

No data available.

Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

Endocrine disrupting properties

No data available.

Other adverse effects

No data available.

SECTION 13: Disposal considerations

Disposal methods

Product disposal

Offer surplus and non-recyclable solutions to a licensed disposal company.

Packaging disposal

Dispose of as unused product.

Waste treatment

No data available

Sewage disposal

Do not let product enter drains

Other disposal recommendations

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

SECTION 14: Transport information

DOT (US)

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Canadian Domestic Substances List (DSL)

Chemical name: Hydrogen peroxide (H2O2)

CAS: 7722-84-1

Chemical name: Hydrochloric acid

CAS: 7647-01-0

Chemical name: 3(2H)-Isothiazolone, 5-chloro-2-methyl-, mixt. with 2-methyl-3(2H)-isothiazolone

CAS: 55965-84-9

Chemical name: Sodium azide (Na(N3))

CAS: 26628-22-8

Chemical name: 1H-Imidazole

CAS: 288-32-4

Chemical name: Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.

CAS: 9005-64-5

Canadian Non-Domestic Substances List (NDSL)

Chemical name: [1,1'-Biphenyl]-3,3',4,4'-tetramine

CAS: 91-95-2

Massachusetts Right To Know Components

Hydrogen peroxide CAS number: 7722-84-1

Chemical name: Hydrochloric acid

CAS number: 7647-01-0

Chemical name: Sodium azide (Na(N3))

CAS number: 26628-22-8

No components are subject to the Massachusetts Right to Know Act

New Jersey Right To Know Components

Water

CAS-number: 7732-18-5 Hydrogen peroxide CAS number: 7722-84-1

Common name: HYDROGEN CHLORIDE

CAS number: 7647-01-0

Common name: SODIUM AZIDE

CAS number: 26628-22-8

Biphenyl-3,3',4,4'-tetrayltetraamine

CAS-No. 91-95-2

Polyoxyethylene sorbitan monolaurate

CAS-No. 9005-64-5

Pennsylvania Right To Know Components

Water

CAS-number: 7732-18-5 Hydrogen peroxide

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CAS number: 7722-84-1

Chemical name: Hydrochloric acid

CAS number: 7647-01-0

Chemical name: Sodium azide CAS number: 26628-22-8

Biphenyl-3,3',4,4'-tetrayltetraamine

CAS-No. 91-95-2

Polyoxyethylene sorbitan monolaurate

CAS-No. 9005-64-5

SARA 302 Components

The following components are subject to reporting levels established by SARA Title III, Section 302:

Hydrogen peroxide CAS-Number: 7722-84-1

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 311/312 Hazards

Reactivity Hazard, Acute Health Hazard, Chronic Health Hazard

Acute Health Hazard

Acute Health Hazard, Chronic Health Hazard

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III. Section 313.

Seveso Directive

Yes. H2 -acute toxic. E1

15.2 Chemical Safety Assessment

The supplier of this product has not conducted any Chemical Safety Assessment

SECTION 16: Other information

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16.1 Further information/disclaimer

DISCLAIMER: The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigation to determine the suitability of information for their particular purposes. In no event shall Diagnostic BioSystems be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, whatsoever arising, even if Diagnostic BioSystems has been advised of the possibility of such damages.

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