

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product Identifier

SDS # BIO-018-EU
Product Code 1081, 1081-1
Product Name PSA Rapid Test

1.2. Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Recommended Use Detects PSA as low as 4 ng/mL for prostate cancer

1.3. Details of the Supplier of the Safety Data Sheet

Supplier

Biomerica
17571 Von Karman Avenue
Irvine, CA 92614, USA

For further information, please contact

Contact Point Biomerica: (949) 645-2111
Email Address bmra@biomerica.com

1.4. Emergency telephone number

Emergency Telephone (24 hr) INFOTRAC 1-352-323-3500 (International)
1-800-535-5053 (North America)

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

2.2. Label Elements

Product Identifier

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

Signal Word

None

2.3. Other Hazards

No information available

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Chemical Nature

This product is an article.

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

Section 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

Eye Contact	Rinse immediately with plenty of water and seek medical advice.
Skin Contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Inhalation	Remove to fresh air.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

4.2. Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms	None known.
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4.3. Indication of any Immediate Medical Attention and Special Treatment Needed

Notes to Physician	Treat symptomatically.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media

Not determined.

5.2. Special Hazards Arising from the Substance or Mixture

Thermal decomposition can lead to release of irritating and toxic gases and vapors.

5.3. Advice for Firefighters

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment as required.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

Personal Precautions

Use personal protective equipment as required.

For Emergency Responders

Use personal protection recommended in Section 8.

6.2. Environmental Precautions

Prevent from entering into soil, ditches, sewers, waterways and/or groundwater. See Section 12, Ecological Information.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Clean-Up Place in appropriate containers for disposal.

6.4. Reference to Other Sections

See Section 13: DISPOSAL CONSIDERATIONS.

Section 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Advice on Safe Handling

Ensure adequate ventilation, especially in confined areas.

General Hygiene Considerations

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions

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

7.3. Specific End Use(s)

Specific Use(s)

Detects PSA as low as 4 ng/mL for prostate cancer.

Risk Management Methods (RMM)

The information required is contained in this Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Exposure Limits

The following information is given as general guidance.

8.2. Exposure Controls

Engineering Controls

Ensure adequate ventilation, especially in confined areas.

Personal Protective Equipment

Eye/Face Protection

Avoid contact with eyes.

Hand Protection

Gloves are not required for normal use.

Skin and Body Protection

Other protective equipment not required under normal use.

Respiratory Protection

Ensure adequate ventilation, especially in confined areas.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	Article		
Appearance	Solid membrane containing dried ingredients and laminated to a plastic strip	Odour	Not determined
Colour	Not determined	Odour Threshold	Not determined
<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>	
pH	7.2 +/- 0.2		
Melting Point/Freezing Point	Not applicable		
Boiling Point/Boiling Range	Not applicable		
Flash Point	Not applicable		
Evaporation Rate	Not determined		
Flammability (Solid, Gas)	Not determined		
Flammability Limits in Air			
Upper Flammability Limits	Not applicable		
Lower Flammability Limit	Not applicable		
Vapour Pressure	Not determined		

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Vapour Density	Not determined	
Specific Gravity	Not determined	
Water Solubility	Not determined	
Solubility(ies)	Not determined	
Partition Coefficient	Not determined	
Auto-ignition Temperature	Not determined	
Decomposition Temperature	Not determined	
Kinematic Viscosity	Not determined	
Dynamic Viscosity	Not determined	
Explosive Properties	Not determined	
Oxidising Properties	Not determined	

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Not reactive under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of Hazardous Reactions

Possibility of Hazardous Reactions

None under normal processing.

10.4. Conditions to Avoid

Keep out of reach of children.

10.5. Incompatible Materials

None known based on information supplied.

10.6. Hazardous Decomposition Products

None under normal use conditions.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity

Product Information

Product does not present an acute toxicity hazard based on known or supplied information.

Inhalation	Not an expected route of exposure.
Eye Contact	Not an expected route of exposure.
Skin Contact	Avoid contact with skin.
Ingestion	Not an expected route of exposure.

The following values are calculated based on chapter 3.1 of the GHS document: mg/kg

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Polyoxyethylene mono(octylphenyl) ether	= 1800 mg/kg (Rat)		
Sodium phosphate dibasic	= 17 g/kg (Rat)		
Polyvinyl alcohol	> 20 g/kg (Rat)		

Skin corrosion/irritation

Not classified.

Serious eye damage/eye irritation	Not classified.
Sensitization	Not classified.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified.
Reproductive toxicity	Not classified.
STOT - single exposure	Not classified.
STOT - repeated exposure	Not classified.
Aspiration hazard	Not classified.

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

12.2. Persistence and Degradability

Not determined.

12.3. Bioaccumulative Potential

Not determined.

12.4. Mobility in Soil

Mobility

Not determined.

12.5. Results of PBT and vPvB Assessment

Not determined.

12.6. Other Adverse Effects

Not determined.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste from Residues / Unused Products

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging

Improper disposal or reuse of this container may be dangerous and illegal.

Section 14: TRANSPORT INFORMATION

IMDG

14.2 Proper Shipping Name Not regulated

RID

14.2 Proper Shipping Name Not regulated

ADR

14.2 Proper Shipping Name Not regulated

ICAO (air)

14.2 Proper Shipping Name Not regulated

IATA

14.2 Proper Shipping Name Not regulated

Section 15: REGULATORY INFORMATION**15.1. Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture****European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Does not apply

International Inventories

Not determined.

TSCA	-
EINECS/ELINCS	-
DSL/NDL	-
PICCS	-
ENCS	-
IECSC	-
AICS	-
KECL	-

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

Section 16: OTHER INFORMATION**Full text of H-Statements referred to under sections 2 and 3**

Not applicable

Classification Procedure

Calculation method

Issue Date: 23-Jun-2015

Revision Date: 03-Jul-2015

Revision Note: New format.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006, as amended by Regulation (EU) No. 453/2010

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet