MATERIALS SAFETY DATA SHEET

According to the regulations (EC) N:o 1907/2006, (EC) N:o 1272/2008 and (EU) N:o 453/2010

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

1.1 Product identifier : **PARAMCARE® H. Pylori Ag Rapid Test**

Pack Size

REF	Pack Size
01 Tests	PHPA **01**
05 Tests	PHPA **05**
10 Tests	PHPA **10**
25 Tests	PHPA **25**
50 Tests	PHPA **50**

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

Relevant Uses: For in vitro diagnostic use only.

PARAMCARE® **H. Pylori Ag Rapid Test)** is a rapid chromatographic immunoassay for the qualitative detection of H. Pylori Ag in stool sample.

1.3 Details of the supplier of the Safety Data Sheet

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

Email: PARAMCARE@paramcarelifesciences.com, Website: www.paramcarelifesciences.com

1.4 Emergency telephone number

Emergency telephone in India: 112 (102 & 108)

24x7 Toll free Helpline / Virtual Assistant (Voice Web) contact number for authenticated health information developed by the National Health Portal (NHP): 1800-180-1104

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

CLP Regulation (EC) No 1272/2008

Classification of this product has been carried out in accordance with CLP regulation (EC) No. 1272/2008.

The PARAMCARE® **H. Pylori Ag Rapid Test does not contains** as hazardous materials

2.2 Label elements

Labeling according Regulation (EC) No 1272/2008

2.3 Other hazards

None

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substance:

Non-Applicable

3.2 Mixture:

Chemical Description: Mixture of substances

Components:

In Accordance with Annex II of regulation (EC) No. 1907/2006 Point 3, the Product Contains

Substance name	CAS-, EC- or index number	REACH Registration No.	Classification	Concentration
Sodium azide	CAS- No.: 26628-22-8 EC-No.: 247-852-1	-	Hazardous classification will be applicable when concentration reaches >0.1%.	0.1%

SECTION 4: FIRST AID MEASURES

4.1 Description of First Aid Measures

When working with the mixture, take care of personal hygiene and prevent contamination of work clothing and skin. If you have any doubts or when symptoms persist, seek medical attention.

By Inhalation

This Product Does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By Skin Contact

This Product Does not contain substances classified as hazardous for inhalation, however, in case of Skin contact it is recommended to remove contaminated cloths and shoes, rinse skin or if necessary shower the affected person thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor

By Eye Contact

Rinse thoroughly with water for atleast 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case removal could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By Ingestion / aspiration

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the affected person at rest. Rinse out mouth and throat, as they may have been affected during ingestion.

4.2 Most important symptoms and effects, both acute and delayed

Non applicable

4.3 Indication of any immediate medical attention and special treatment needed

Non applicable

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing Media

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC Powder), in accordance with Regulation of the fire protection systems. **5.2 Special hazards arising from the substance or mixture** Protective clothing, breathing apparatus.

5.3 Advice for firefighters

Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Observe the principles of work safety in chemical laboratories. Do not eat, drink or smoke.

Avoid contact. Do not get in eyes, on skin, or clothing.

PROCEDURE TO BE FOLLOWED IN CASE OF LEAK OR SPILL: Ventilate the area. Wear appropriate personal protective equipment as specified in Section 8. Contain and recover liquid when possible. Collect liquid in an appropriate container or absorb with an inert material and place in waste container. Wash surrounding area.

6.2 Environmental precautions

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up

Absorb spilled agent with a suitable inert material (sand, earth, vapex) and store contaminated material in containers for collection of hazardous waste. For waste disposal see item 13.

Sweep solid reagent and store in containers for collection of hazardous waste. For waste disposal see item 13.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Observe the principles of work in laboratory. Observe the normal operating procedures for handling chemical substances and mixtures. Do not eat, drink or smoke. Use personal protective equipment.

7.2 Conditions for safe storage, including any incompatibilities

Store according to the package insert instructions.

7.3 Specific end use(s)

The kit is designed for in vitro diagnostic devices. Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

National occupational exposure limit values

Exposure limits not available.

Other limit values

-

DNE

L

-

PNE

C

-

8.2 Exposure controls

Appropriate engineering controls

-

Eye / face protection

Protective goggles recommended.

Skin protection

Lab coat recommended.

Hand protection

Wear protective gloves (nitrile or butyl rubber).

Respiratory protection

-

Thermal hazards

-

Environmental exposure controls

No special engineering controls are required when working with this product. Handle in accordance with good hygiene and safety practice.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on physical and chemical properties

Appearance	Clean and non dusty assembled cassette, no pen/ink marking on NCM, Clear liquid Assay Buffer
Odor	not available

Odor threshold	not available
pH	not available
Melting point/freezing point	not available
Initial boiling point and boiling range	≥ 100°C
Flash point	< 100°C
Evaporation rate	not available
Flammability (solid, gas)	not available
Upper/lower flammability or explosive limits	not available
Vapor pressure	not available
Vapor density	not available
Relative density	not available
Solubility(ies)	not available
Partition coefficient: n-octanol/water	not available
Auto-ignition temperature	not available
Decomposition temperature	not available
Viscosity	not available
Explosive properties	not available
Oxidizing properties	not available

9.2 Other information

The other physical and chemical properties of PARAMCARE® **H. Pylori Ag Rapid Test** have not been investigated

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No Data Available

10.2 Chemical stability

No Data Available

10.3 Possibility of hazardous reactions

No Data Available

10.4 Conditions to avoid

No Data Available

10.5 Incompatible materials

No Data Available

10.6 Hazardous decomposition products

No Data Available

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects Acute toxicity No data available.

Skin corrosion/irritation
No Data Available

Serious eye damage/irritation
No Data Available

Respiratory or skin sensitisation
No Data Available

Germ cell mutagenicity
No data available.

Carcinogenicity No data available.

Reproductive toxicity
No data available.

STOT-single exposure
No data available.

STOT-repeated exposure
No data available.

Aspiration hazard No data available. **Other information** No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No Data Available

12.2 Persistence and degradability

No Data Available

12.3 Bioaccumulative potential

No Data Available

12.4 Mobility in soil

No Data Available

12.5 Results of PBT and vPvB assessment

No Data Available

12.6 Other adverse effects

No Data Available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of waste materials, unused components and contaminated packaging in compliance with country and local regulations. If unsure of the applicable requirements, contact the authorities for information.

SECTION 14: TRANSPORT INFORMATION

Not subject to transport regulation.

14.1 UN Number

-

14.2 UN proper shipping name

-

14.3 Transport hazard class(es)

-

14.4 Packing group

-

14.5 Environmental hazards

-

14.6 Special precautions for user

-

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

-

SECTION 15: REGULATORY INFORMATION

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

-

15.2 Chemical safety assessment

-

SECTION 16: OTHER INFORMATION

Indication of changes

-

Abbreviations and acronyms

-

Key literature references and sources for data

-

Used method in evaluating classification

-

List of relevant safety and precautionary statements

-

Training advice for workers: It is recommended to train the laboratory employees before use of this preparation.

Sources of key data used to compile the Material Safety Data Sheet: The collected information is based on the regulations (EC) No 1907/2006, (EC) No 1272/2008 and (EU) No 453/2010.

Information given is based on our best knowledge and is intended to describe the product for the purposes of safety of transporting and handling only. It should not be therefore construed as guaranteeing any specific property of the product. It is the responsibility of the user to observe all current regulations and consider recommendations on the use of application of product.

Declaration

The safety data sheet contains basic data corresponding to the present state of our knowledge and experience, in accordance with applicable regulations. The foregoing information was gathered with the utmost care, but that does not mean that it is complete and should be used as the only correct information.