

## PRODUCT SAFETY DATA SHEET

According to the regulations (EC) No: 1907/2006, (EC) No: 1272/2008 and (EU) No: 453/2010

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

**1.1 Product identifier : Amylase Test Kit**

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

Relevant Uses: For in vitro diagnostic use only.

Amylase Test Kit is intended for quantitative measurement of Amylase concentration in serum and Plasma.

**1.3 Details of the supplier of the Safety Data Sheet**

Param care Lifesciences Pvt. Ltd.  
G/F-12/13, Evershine 2, Survey No. 307/3/1, Balitha, N.H.No.48, Vapi 396191, Dist: Valsad Gujarat, India  
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### 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 **Amylase Test Kit is not classified** as a dangerous Device

**2.2 Label elements**

NA

**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	26628-22-8	-	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 at least 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**

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**DNEL**

-

**PNEC**

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**8.2 Exposure controls****Appropriate engineering controls**

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**Eye / face protection**

Protective goggles recommended.

**Skin protection**

Lab coat recommended.

**Hand protection**

Wear protective gloves (nitrile or butyl rubber).

**Respiratory protection**

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**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**

<b>Appearance</b>	Reagent-1: Clear, Colorless, liquid reagent Reagent-2: Clear, Colorless, liquid reagent Standard: Clear, Colorless, liquid reagent
<b>Odor</b>	not available
<b>Odor threshold</b>	not available
<b>pH</b>	not available
<b>Melting point/freezing point</b>	not available
<b>Initial boiling point and boiling range</b>	$\geq 100^{\circ}\text{C}$
<b>Flash point</b>	$< 100^{\circ}\text{C}$
<b>Evaporation rate</b>	not available
<b>Flammability (solid, gas)</b>	not available
<b>Upper/lower flammability or explosive limits</b>	not available

<b>Vapor pressure</b>	not available
<b>Vapor density</b>	not available
<b>Relative density</b>	not available
<b>Solubility(ies)</b>	not available
<b>Partition coefficient: n-octanol/water</b>	not available
<b>Auto-ignition temperature</b>	not available
<b>Decomposition temperature</b>	not available
<b>Viscosity</b>	not available
<b>Explosive properties</b>	not available
<b>Oxidizing properties</b>	not available

## 9.2 Other information

The other physical and chemical properties of Amylase Estimation Kit 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 sensitization

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 Bio accumulative 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**

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**14.2 UN proper shipping name**

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**14.3 Transport hazard class(es)**

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**14.4 Packing group**

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**14.5 Environmental hazards**

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**14.6 Special precautions for user**

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

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**SECTION 15: REGULATORY INFORMATION****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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**15.2 Chemical safety assessment**

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**SECTION 16: OTHER INFORMATION**

**Indication of changes**

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**Abbreviations and acronyms**

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**Key literature references and sources for data**

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**Used method in evaluating classification**

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**List of relevant safety and precautionary statements**

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**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 Product 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.***