

 PARAMCARE LIFE SCIENCES PVT. LTD. <i>where innovation starts....</i>	PARAMCARE LIFE SCIENCES PRIVATE LIMITED	
	MATERIAL SAFETY DATA SHEET	
Research & Development	TITLE: Bilirubin (Total) Test Kit	Doc. No: PCL-MSDS-BC-BIT-00
		Effective date: 10/02/2023
		Review date: 09/02/2026
		Supersedes: NA

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	: Bilirubin (TOTAL) Test Kit
1.2 Relevant identified uses of the substance or mixture and uses advised against	Relevant Uses: For in vitro diagnostic use only. Bilirubin (TOTAL) Test Kit is intended for quantitative measurement of Bilirubin (TOTAL) 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.

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 Bilirubin (TOTAL) 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	0.1%

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			reaches 0.1%.	
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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.

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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

-

DNEL

-

PNEC

-

8.2 Exposure controls

Appropriate engineering controls

-

Eye / face protection

Protective goggles recommended.

Skin protection

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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	Reagent: Clear, Colorless, liquid reagent Reagent: Clear, Colorless, liquid reagent
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 Bilirubin (TOTAL) 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

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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

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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

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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
<i>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.</i>