

**Works:**Plot Nos. M 46 - 47, Phase III B, Verna Industrial Estate,  
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E-mail: [zephyr@tulipgroup.com](mailto:zephyr@tulipgroup.com)**SAFETY DATA SHEET  
FIAcheck™ PRL Device**

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**Section 1: Identification of the substance /mixture and of the company undertaking****1.1 Product identifier****Product name:** FIAcheck™ PRL Device**Product code:** 535030025**1.2 Relevant identified uses of the substance or mixture and uses advised against****Use of substance/mixture:** Fluorescence Immunoassay intended for Quantitative determination of Prolactin (PRL) in human Serum. This reagent is intended for IN VITRO diagnostic use only. NOT FOR USE IN HUMANS.**1.3 Details of the supplier of the safety data sheet****Company name:** Zephyr Biomedicals,  
A Division of Tulip Diagnostics (P) Ltd.  
Plot nos. M 46-47, Phase III B,  
Verna Industrial Estate,  
Verna, Goa - 403 722,  
INDIA.  
[www.tulipgroup.com](http://www.tulipgroup.com)**Tel:** +91 (0832) 6682000 / 6624502**Fax:** (0832) 6680156**Email:** [zephyr@tulipgroup.com](mailto:zephyr@tulipgroup.com)**1.4 Emergency telephone number****Emergency tel:** +91 (0832) 6682000 / +91 (0832) 6624502  
(office hours only)

Issue No. 02

Issue date: 08-12-2023

Sign/Date:

(QC Dept.)

**Zephyr Biomedicals**  
A Division of Tulip Diagnostics (P) Ltd.**Corporate Office:** Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Bambolim Complex  
Post Office, Goa - 403 202, INDIA. Tel.: (0832) 2458546-51, Fax: (0832) 2458544.  
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**Section 2 : Hazards identification****2.1 Classification of the substance or mixture**

**Classification under CLP:** This product has no classification under CLP.

The product is regulated as an in vitro diagnostic medical device and is not considered hazardous in accordance with regulation (EC) No.1272/2008.

**2.2 Label elements**

**Label elements:** None are present.

**Precautionary statements:** P102: Keep out of reach of children.

P234: Keep only in original container.

**2.3 Other hazards**

**PBT:** This product is not identified as a PBT/vPvB substance.

**Section 3 : Composition /information on ingredients****3.1 Substances**

**Chemical identity:** In-vitro Diagnostic test for quantitative determination of Prolactin (PRL) in human Serum

**Contains:** Contains no hazardous substances in reportable quantities under the CLP.

**Section 4 : First aid measures****4.1 Description of first aid measures**

**Skin contact:** Wash immediately with plenty of soap and water

**Eye contact:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so.  
Continue rinsing. If eye irritation persists, seek medical advice/attention.

**Ingestion:** Do not induce vomiting. Wash mouth with water and give plenty of water to drink immediately. Obtain medical attention if necessary and show label on container.

**Inhalation:** Irritation is unlikely to occur but in the event of discomfort, provide plenty of fresh air and if necessary seek medical assistance.

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**4.2 Most important symptoms and effects, both acute and delayed**

**Skin contact:** There may be mild irritation at the site of contact.  
**Eye contact:** There may be irritation and redness.  
**Ingestion:** There may be irritation of the throat.  
**Inhalation:** No symptoms.

**4.3 Indication of any immediate medical attention and special treatment needed**

**Immediate / special treatment:** Not applicable.

**Section 5: Fire -fighting measures****5.1 Extinguishing media**

**Extinguishing media:** Suitable extinguishing media such as carbon dioxide, dry chemical powder or polymer foam for the surrounding fire should be used.  
Use water spray to cool containers.

**5.2 Special hazards arising from the substance or mixture**

**Exposure hazards:** No known specific hazards

**5.3 Advice for fire fighters**

**Advice for fire-fighters:** Do not enter fire without proper protective equipment, including respiratory protection.

**Section 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

1. Follow Standard Biosafety guidelines during handling of potentially infectious human specimens.
2. Refer to section 8 of SDS for personal protection details.

**6.2 Environmental precautions**

**Environmental precautions:** Do not discharge into drains or rivers.

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#### 6.3 Methods and material for containment and cleaning up

**Clean-up procedures:** For small spills, clean up with paper/cloth, or mop up, and dispose off safely.  
Clean area of spillage down with plenty of water.

#### 6.4 Reference to other sections

**Reference to other sections:** Refer to section 8 of SDS.

### Section 7: Handling and storage

#### 7.1 Precautions for safe handling

**Handling requirements:** Refer IFU for FIAcheck™ PRL Device.

#### 7.2 Conditions for safe storage, including any incompatibilities

**Storage conditions:** Store in original container between 4°C to 30°C.

**Suitable packaging:** Must only be kept in original packaging.

#### 7.3 Specific end use(s)

**Specific end use(s):** Refer Section 1.2

### Section 8: Exposure controls/personal protection

#### 8.1 Control parameters

**Workplace exposure limits:** Contains no substance with occupational exposure limit values.

#### DNEL/PNEC Values

**DNEL / PNEC:** No data available.

#### 8.2 Exposure controls

**Engineering measures:** Ensure all engineering measures mentioned in section 7 of SDS are in place.

**Respiratory protection:** Respiratory protection not required. Ensure adequate ventilation.

**Hand protection:** Disposable gloves.

**Eye protection:** No specific measures are required when using good safe practice.

**Skin protection:** Protective clothing not required in normal use. Use proper glove removal technique to avoid skin contact.

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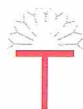
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**Section 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

	Device
State :	Solid
Colour :	White
Odour :	Odourless
Solubility in water :	Insoluble
Viscosity :	Not Applicable
Boiling point/range°C:	No data available
Flash point°C:	No data available
Vapour pressure:	No data available
Melting point/range°C:	No data available
Auto flammability°C:	No data available
Relative density:	No data available

**9.2 Other Information**

Other information: No data available.

**Section 10: Stability and reactivity****10.1 Reactivity**

Reactivity: Stable under recommended transport or storage conditions.

**10.2 Chemical stability**

Chemical stability: Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.

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**10.4 Conditions to avoid**

Conditions to avoid: Heat and moisture

**10.5 Incompatible materials**

Materials to avoid: Strong acids /alkalines, oxidising / reducing agents.

**10.6 Hazardous decomposition products**

Hazardous decomposition products: No known hazardous decomposition products are formed in high quantities.

**Section 11: Toxicological information****Section 11.1 Information on Toxicological effects**

Toxicity values: No data available.

**Symptoms/routes of exposure**

Skin contact: There may be mild irritation at the site of contact

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms.

**Section 12: Ecological information****12.1 Toxicity**

Ecotoxicity values: No data available.

**12.2 Persistence and degradability**

Persistence and degradability: No data available.

**12.3 Bioaccumulative potential**

Bioaccumulative potential: No data available.

**12.4 Mobility in soil**

Mobility: No data available.

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**12.5 Results of PBT and vPvB assessment****PBT identification:** This product is not identified as a PBT/vPvB substance.**12.6 Other adverse effects****Other adverse effects:** Negligible ecotoxicity.**Section 13: Disposal considerations****13.1 Waste treatment methods****Disposal operations:** Dispose off in accordance with current legislation and local authority regulations as per established safety procedures.**NB:** The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.**Section 14: Transport information****14.1 UN number****UN number:** N/A**14.2 UN proper shipping name****Shipping name:** This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).**14.3 Transport hazard class(es)**

Non -hazardous for transport.

**14.4 Packing group**

N/A

**14.5 Environmental hazards****Environmentally hazardous :** No**Marine pollutant:** No

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**14.6 Special precautions for user****Special precautions:**

1. Shipper boxes should be arranged / stacked in the direction as indicated the shipper label/ Carton.
2. Avoid over-stacking. Do not stack more than 5 boxes.

**Section 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

**Specific regulations:** Applicable national / regional or local regulations.

Safe for all kinds of modes of transportation.

**15.2 Chemical Safety assessment**

Not carried out for this product.

**Section 16: Other information**

**Other information:** This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

**Legal disclaimer:** The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

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