



**Works:**

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**SAFETY DATA SHEET  
FIAcheck™ FSH Device**

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**Section 1: Identification of the substance /mixture and of the company undertaking**

**1.1 Product identifier**

**Product name:** FIAcheck™ FSH Device

**Product code:** 535010025

**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 FSH (Follicle Stimulating Hormone) 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,  
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[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  
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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 FSH (Follicle Stimulating Hormone) 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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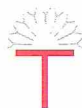
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**4.2 Most important symptoms and effects, both acute and delayed**

**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™ FSH 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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**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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