

**Works:**

Plot Nos. M 46 - 47, Phase III B, Verna Industrial Estate,  
Verna, Goa - 403 722, INDIA.

Tel.: (0832) 6624502 / 6682000, Fax: (0832) 6680156.

E-mail: [zephyr@tulipgroup.com](mailto:zephyr@tulipgroup.com)

**SAFETY DATA SHEET**  
**BabySafe™**  
**17-OHP Rapid Diagnostic Test**

**Section 1: Identification of the substance/mixture and of the company undertaking****1.1 Product identifier**

**Product name:** BabySafe™ 17OHP Rapid Diagnostic Test

**Product code:** 526020010

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

**Use of substance/mixture:** Immunochromatographic assay for the semi-quantitative detection of 17 Alpha-hydroxyprogesterone (17-OHP) in New Born whole blood samples. It is to be used for screening. 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. M46-47, Phase III B,

Verna industrial Estate.

Verna, 403 722

Goa, 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).

**Section 2: Hazard's 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.

*[Signature]*  
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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 detection of 17 Alpha-hydroxyprogesterone (17-OHP) in New Born whole blood samples.**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

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

Follow standard biosafety guidelines during handling of potentially infectious human specimens.

**6.2 Environmental precautions 6.2 Environmental**

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

**6.3 Methods and material for containment and clean up**

**Clean-up procedures:** For small spills, cleanup 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**

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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 BabySafe™ 17-OHP Rapid Diagnostic Test**7.2 Conditions for safe storage, including any incompatibilities****Storage conditions:** Store in original container between 4 deg C to 30 deg C. Keep buffer container tightly closed and once opened must be carefully closed back and kept in upright position to prevent leakage.**Suitable packaging:** Must only be kept in original packaging.**7.3 Specific end use(s)****Specific end use(s):** Use as per Instructions for Use.**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. Face mask – recommended.**Hand protection:** Protective Disposable gloves  
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**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.

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

	Device	Assay Buffer
State :	Solid	Liquid
Colour :	White	Colourless
Odour :	Odourless	Odourless
Solubility in water :	Insoluble	Not Applicable
Viscosity :	Not Applicable	No data available
Boiling point/range°C:	No data available	No data available
Flash point°C:	No data available	No data available
Vapour pressure:	No data available	No data available
pH:	No data available	7.6
Melting point/range°C:	No data available	No data available
Auto flammability°C:	No data available	No data available
Relative density:	No data available	1.0

  
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**Section 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 recommended transport or storage conditions.

**10.3 Possibility of hazardous reactions**

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

**10.4 Conditions to avoid**

**Conditions to avoid:** Heat and moisture.

**10.5 Incompatibility materials**

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

**10.6 Hazardous decomposition products**

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



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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 Transportation hazard class(es)**

Non-hazardous for transport.

**14.4 Packing group**

N/A

**14.5 Environmental hazards****Environmental hazards:** No**Marine pollutant:** No**14.6 Special precautions for user****Special precautions:** 1. Shipper boxes should be arranged / stacked in the direction as indicated on the shipper label / carton.

2. Avoid over stacking, do not stack more than 5 boxes.

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

**Special 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 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.

*[Signature]*  
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