

PRODUCT SAFETY DATA SHEET

EARLY DETECTION PREGNANCY TEST, ONE STEP PREGNANCY TEST

Code: 7SDS-0128
Print Date: 14-Jun-2023

Rev: 2
Status: Current

Effective Date: 24-May-2023
Document valid for use on date of printing.

The products to which this safety data sheet refers are articles¹, not mixtures or substance and the components of the articles are not designed to be released from the article under normal conditions of use. Therefore there is no requirement to provide a safety data sheet. This document is provided as reference information for the safe handling of the product.

SECTION 1: Product and Company Identification

Name of Product	EARLY DETECTION PREGNANCY TEST, ONE STEP PREGNANCY TEST
Device Model	CB16, CB17, CYGNUS
Product Type	<i>In vitro</i> diagnostic medical device
Name of Company	SPD Swiss Precision Diagnostics GmbH
Address	c/o SPD Development Company Ltd, Priory Business Park, Bedford, MK44 3UP, United Kingdom
Emergency Contact	US 1-800-321-EASY (3279) (Mon-Fri 8.30 am – 5 pm EST) Outside US +44 203 684 7289 (Mon-Fri 7am – 3 pm UK time, excluding UK public holidays)
Email address	spdproductsupport@spdspark.com

SECTION 2: Hazards Identification

Classification	As an article this product is exempt from OSHA's hazard communication standard 29 CFR 1910.1200 Not classified as dangerous for supply/use according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended)
Other Hazards	If disassembled small parts may present a choking hazard

SECTION 3: Composition/Information on Ingredients

Test stick	Test strip impregnated with dried chemical/biochemical reagent & non-toxic zeolite desiccant tablet to absorb moisture, contained inside plastic case and sealed in a foil pouch.
Labelling Requirements	The product does not need to be labelled in accordance with OSHA's hazard communication standard 29 CFR 1910.1200 or CLP

SECTION 4: First Aid Measures

The following first aid measures are only relevant in the event of serious misuse, whereby the test stick or holder are disassembled.	
Ingestion/swallowing	If any components are accidentally swallowed seek medical attention. If any components are chewed or sucked, rinse out the mouth with water. Seek medical attention if any adverse symptoms are present. Keep out of the reach of children

SECTION 5: Firefighting Measures

Fire extinguishing agent	Water spray, foam, dry powder or CO ₂
Extinguishing method	As appropriate to surrounding conditions. Wear full protective suit and self-contained breathing apparatus.
Additional Information	The test stick contains combustible materials

¹ Definition of an article according to REACH: An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.
Definition of an article according to 29CFR 1910.1200(c) Article means a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical, and does not pose a physical hazard or health risk to employees.

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SECTION 6: Accidental Release Measures	
N/A	
SECTION 7: Handling and Storage	
Safe Handling	Keep out of the reach of children, follow instructions for use provided with the product.
Storage	Store at 2-30°C
SECTION 8: Exposure Controls and Personal Protection	
The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace. Personal protective equipment is not required under normal conditions of storage and use.	
SECTION 9: Physical and Chemical Properties	
Refer to section 3	
SECTION 10: Stability and Reactivity	
Stability	The product is stable when stored dry at 2-30 °C
SECTION 11: Toxicological Information	
N/A	
SECTION 12: Ecological Information	
The device contains plastic and other components that are not readily degradable.	
SECTION 13: Disposal Considerations	
Product & Packaging	Disposal must be made in accordance with local waste management regulations Instructions for disposal are provided in the instructions for use.
SECTION 14: Transport Information	
Not classified as dangerous for transport	
SECTION 15: Regulatory Information	
Classification, labelling and packaging of substances and mixtures Regulation (EC) No 1272/2008 Consumer Product Safety Regulations 16CFR 1600 In Vitro Diagnostics Medical Devices Directive 98/79/EC In Vitro Diagnostics Medical Device Regulation (IVDR) 2017/746 IVD Product Labelling 21 CFR 809 OSHA Hazard Communication Standard 29CFR 1910.1200	
SECTION 16: Other Information	
This safety data sheet is provided as reference information in order to handle the product safely. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.	
Prepared by	Regulatory Affairs Department, SPD Development Company Ltd. spdproductsupport@spdspark.com