Corresponding to EC Directive 93/112/EC

Date of Issue: 12 May 2020 Replaces the version of: 09 April 2015



Trade Name: VITA® AFB and EFB DIAGNOSTIC DEVICES

1. Identification of the Product and of the Company.

1.1 Product name:

VITA AFB DIAGNOSTIC DEVICE and VITA EFB DIAGNOSTIC DEVICE

1.2 Company name:

VITA (EUROPE) LIMITED

BASINGSTOKE, HAMPSHIRE, UNITED KINGDOM

Telephone: +44 (0) 1256 473 177

1.3 Emergency Telephone Number: +44 (0) 1256 473 175

+44 (0) 7767 815 370 +44 (0) 1252 873 819

2. Composition / Information on Ingredients

Chemical characterisation of the preparation:

The monoclonal antibodies used in the test are: AFB (American Foulbrood) or EFB (European Foulbrood).

3. Hazards Identification

No significant hazard for the device; refer to MSDS for the accompanying buffer solution supplied with the test kit also.

4. First Aid Measures: Standard Procedures apply

- 4.1 After contact with the eyes: Not applicable
- 4.2 After contact with the skin: Not applicable
- 4.3 After inhalation: Not applicable
- 4.4 After ingestion: Not applicable

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5. Fire Fighting Measures: Standard Methods

5.1 Suitable extinguishing media:

Alcohol-resistant foam, carbon dioxide dry powder.

Extinguishing media not to be used: Not applicable

5.2 Special protective equipment for fire-fighters:

Wear self-contained breathing apparatus

- 5.3 Special advice in case of fire: Not applicable
- 5.4 Hazardous products of combustion:

Potentially toxic phenol vapours from plastics.

6. Accidental Release Measures

Not applicable

7. Handling and Storage

7.1 Handling:

Measures to prevent fire and explosion:

No special measures required.

7.2 Storage:

Technical protective measures: Do not freeze.

Maximum storage temperature: up to 30°C; ideally store between 18°C and 25°C. Shelf life in original, sealed, containers: at least 18 months (*current data – stability studies ongoing*)

Store in undamaged, properly sealed, original aluminium foil packaging protected from light. Keep out of direct sunlight. Store in secondary packaging for extra protection.

8. Exposure Controls and Personal Protection

8.1 Exposure controls: Not applicable

8.2 Industrial hygiene:

Keep away from food, drink and animal feedstuffs.

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When using do not eat, drink or smoke.

8.2 (cont.)

Change contaminated clothes immediately.

At works and before taking breaks, wash your hands.

8.3 Personal protective equipment:

Not applicable

9. Physical and Chemical Properties

9.1 Form: Lateral flow device incorporating specific monoclonal

antibodies in a plastic housing.

9.2 Colour: white (AFB kit) or yellow (EFB kit)

9.3 Odour: none

9.4 Change in physical state:

Melting point: not applicable Boiling point: not applicable

9.5 Flash point: not applicable

9.6 Ignition temperature: not applicable

9.7 Explosion limits: not applicable

9.8 Density: not applicable

9.9 Vapour pressure: not applicable

9.10 Viscosity: not applicable

9.11 pH value: not applicable

9.12 Solubility in / Miscibility with water: not applicable

9.13 Partition coefficient n-octanol/water:

Log p O/W: not applicable

10. Stability and Reactivity

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Hazardous decomposition products:

None known.

11. Toxicological information

Not applicable.

12. Ecological Information

Not applicable.

13. Disposal Considerations

Must be disposed of according to the applicable local regulations in force, if no recycling is possible. Packaging that cannot be cleaned should be disposed of as for product.

14. Transportation Information

Regulations Class UN-No. PGr.

RID/ADR: not classified ICAO/IATA-DGR: not classified GGVSee/IMDG-Code: not classified

15. Regulatory Information

Assessment by Vita (Europe) Limited in accordance with EC directives on dangerous substances:

S2 Keep out of the reach of children.

Keep away from food, drink, and animal feedstuffs.

16. Other Information

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as a warranty with regard to the product specific properties.