**Safety Data Sheet**

**Revision date: 06 April 2022**

**Section 1: Identification of Substance/Mixture and of the company/undertaking**

**1.1 Product identifiers**

Product Name: T-SPOT.*COVID*

Product Number: COV.435/200, COV.435/300

REACH Number: A registration number is not available for this substance as the substance or its uses are exempted from registration or the annual tonnage does not require registration

**1.2 Relevant identified uses and uses advised against**

Identified uses: The T-SPOT.*COVID* test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, specifically the T cell response. The T-SPOT.*COVID* test should not be used to diagnose acute SARS-CoV-2 infection.

**1.3 Details of the supplier of the safety data sheet**

Manufacturer/Supplier: Oxford Immunotec Limited

 143 Park Drive East

Milton Park

 Abingdon

 Oxfordshire

 OX14 4SE

 United Kingdom

Telephone: +44 1235 442 780

Fax: +44 1235 442 781

Website: www.oxfordimmunotec.com

**1.4 Emergency Telephone Number**

Emergency Telephone: +44 1235 442 780 *(08:00-17:30)*

**Section 2: Hazards Identification**

**2.1 Classification of substance or mixture (CLP Classification)**

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008 and its amendments

**2.2 Label elements**

None: the product does not need to be labelled in accordance with EC directives or respective national law

* 1. **Other hazards**

None

**Section 3: Composition/information on Components**

**Microtitre Plate (CW.200/CW.300)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Components** | **Function** | **CAS Number** | **EINECS-No.** |
| PVDF | Microfiltration membrane | 24937-79-9 | Unlisted |
| Polyethylene | Underdrain support | 9002-88-4 | Unlisted |
| Acrylic | Plate and cover |  |  |

**Substrate Solution (SR.300)**

 1 Bottle, 25 mL volume

|  |  |  |  |
| --- | --- | --- | --- |
| **Components** | **Weight %** | **CAS Number** | **EINECS-No.** |
| BCIP | 0.03 | 6578-06-9 | 229-506-1 |
| NBT | 0.06 | 298-83-9 | 206-067-4 |

**Conjugate Reagent (CR.300)**

 1 Vial, 50 µL volume

|  |  |  |  |
| --- | --- | --- | --- |
| **Components** | **Weight %** | **CAS Number** | **EINECS-No.** |
| Tris Buffer | 1.4 | 77-86-11185-53-1 | 201-064-4214-684-5 |
| MgCl2 | 0.01 | 7786-30-3 | 232-094-6 |
| ZnCl2 | 0.001 | 7646-85-7 | 231-592-0 |

**Details on hazardous components**

|  |  |  |  |
| --- | --- | --- | --- |
| **Component** | **CAS No.** | **Concentration** | **Classification according to Regulation (EC) No 1272/2008 [CLP]** |
| Zinc Chloride | 7646-85-7 | 0.001 % | **Not hazardous at this concentration** |
| 5-chloro-2-methyl-4-isothiazol-3-oneand2-methyl-4-isothiazol-3-one  | 26172-55-42682-20-4 | 0.000003 %0.000003 % |

**Positive Control (CP.300)**

 2 vials, 0.8 mL volume each (CP.300)

|  |  |  |  |
| --- | --- | --- | --- |
| **Components** | **Weight %** | **CAS Number** | **EINECS-No.** |
| Phytohaemagg-lutinin | 0.0015 | 9008-97-3 | 232-718-7 |
| Dilution media | 99.9985 |  |  |

**COV-A (COVA.435)**

 2 vials, 0.8 mL volume each (COVA.435)

|  |  |  |  |
| --- | --- | --- | --- |
| **Components** | **Weight %** | **CAS Number** | **EINECS-No.** |
| Peptides | 3 |  |  |
| DMSO | 1 | 67-68-5 | 200-664-3 |
| Dilution media | 96 |  |  |

**COV-B (COVB.435)**

 2 vials, 0.8 mL volume each (COVB.435)

|  |  |  |  |
| --- | --- | --- | --- |
| **Components** | **Weight %** | **CAS Number** | **EINECS-No.** |
| Peptides | 3 |  |  |
| DMSO | 1 | 67-68-5 | 200-664-3 |
| Dilution media | 96 |  |  |

**Section 4: First Aid Measures**

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water for at least 15 minutes and seek medical attention.

Ingestion: If ingested, wash out mouth with water, provided person is conscious. Seek medical attention immediately and show the label.

Inhalation: Move to fresh air immediately. If experiencing difficulty breathing, seek medical attention.

Skin contact: Remove contaminated clothing and wash affected area with soap and water. If symptoms of skin irritation appear, seek medical attention.

Protection of first-aiders: Wear suitable gloves and eye/face protection.

Notes to physician: None.

**Section 5: Fire Fighting Measures**

|  |  |
| --- | --- |
| Suitable extinguishing media: | Use any extinguishing media that is suitable for the surrounding fire. |
| Extinguishing media which must not be used for safety reasons: | None. |
| Specific hazards:  | The plastic components of the Microtitre Plates will melt and/or decompose under fire conditions. Once ignited, the plastic materials will add to the intensity of the fire and can be expected to emit hazardous gases, vapours, fumes and smoke particles. |
| Special protective equipment for firefighters: | Wear self-contained breathing apparatus and protective suit for firefighting if necessary. |
| Combustion products or resulting gases: | Carbon monoxide, Carbon dioxide, Nitrogen oxides, Phosphorous oxides, Hydrogen chloride, Hydrogen bromide. |

**Section 6: Accidental Release Measures**

|  |  |
| --- | --- |
| Personal precautions: | Ensure adequate ventilation. Use suitable PPE for size of release and surrounding environment. |
| Environmental precautions: | Waste disposal must be in accordance with appropriate international, national, state and local laws and regulations. |
| Methods for cleaning up: | No special measures are typically required. Wipe any liquid up with inert, adsorbent material and clean contaminated surface thoroughly. |

**Section 7: Handling and Storage**

|  |  |
| --- | --- |
| Precautions for safe handling: | Wear protective safety glasses, gloves and clothing. Wash hands afterwards. |
| Conditions for safe storage: | Keep refrigerated. Do not freeze. |
| Incompatible products: | No special restrictions on storage with other products. |
| Specific use(s): | Apart from the uses stated in 1.2 no other uses are stipulated. |

**Section 8: Exposure Controls/Personal Protection**

**8.1 Control parameters**

Contains no substances with occupational exposure limit values.

**8.2 Exposure controls**

Engineering controls: Ensure adequate ventilation.

Respiratory protection: None required.

Hand protection: Wear disposable gloves while handling the reagent. Wash hands after use.

Eye protection: Wear safety glasses with side-shields.

Skin and body protection: Wear suitable protective clothing.

**8.3 Environmental exposure controls**

Do not let product enter drains

**Section 9: Physical and Chemical Properties**

**9.1 Substrate Solution (SR.300)**

Appearance: Pale yellow liquid

pH: 9.8

**9.2 Conjugate Reagent (CR.300)**

Appearance: Colourless liquid

pH: 7.4

**9.3 Positive Control (CP.300)**

Appearance: Orange/pink liquid

pH: 7.1

**9.4 COV-A (COVA.435)**

Appearance: Orange/pink liquid

pH: 6.8-7.3

**9.5 COV-B (COVB.435)**

Appearance: Orange/pink liquid

pH: 6.8-7.3

**Section 10: Stability and Reactivity**

|  |  |
| --- | --- |
| **10.1 Reactivity****10.2 Chemical stability** | No data available.Stable under recommended storage conditions. |
| **10.3 Possibility of hazardous reactions**  | Under normal conditions hazardous reactions will not occur. |
|  |  |
| **10.4 Conditions to avoid** | None known. |
| **10.5 Materials to avoid** | No data available. |
| **10.6 Hazardous decomposition** **products:**  | Carbon monoxide, Carbon dioxide, Nitrogen oxides, Phosphorous oxides, Hydrogen chloride, Hydrogen bromide. |

**Section 11: Toxicological Information**

**11.1 Information on toxicology effects**

|  |  |
| --- | --- |
| Acute toxicity: | Not classified. No known significant effects or critical hazards. |
| Skin corrosion/irritation: | Not classified. No known significant effects or critical hazards. |
| Serious eye damage/eye irritation: | Not classified. No known significant effects or critical hazards. Splash may cause mild irritation. |
| Respiratory or skin sensitisation: | Not classified. Mild irritation may occur. Some allergic reaction cannot be ruled out. |
| Germ cell mutagenicity: | Not classified. No known significant effects or critical hazards. |
| Carcinogenicity: | Not classified. No data available. |
| Reproductive toxicity: | Not classified. No data available. |
| Aspiration hazard: | Not classified. No data available. |

**Section 12: Ecological Information**

Toxicity: No known significant effects or critical hazards.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data available.

Results of PBT and vPvB: No data available.

Other adverse effects: No data available.

**Section 13: Disposable Consideration**

|  |  |
| --- | --- |
| Waste from residues/unused products: | Waste disposal must be in accordance with appropriateinternational, national, state and local laws and regulations. |
| Contaminated packaging: | Waste disposal must be in accordance with appropriateinternational, national, state and local laws and regulations. |
| Methods for cleaning up: | Wipe up with an inert adsorbent material (e.g. cloth, fleece) and clean contaminated surface thoroughly. |

**Section 14: Transportation Information**

The transport of this product is not regulated by IMO/IMDG, ADR/RID or IATA/ICAO as a hazardous material or dangerous goods.

**Section 15: Regulatory Information**

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

This safety data sheet complies with Regulation (EC) No. 1907/2006 REACH).

The product is judged not to be hazardous to health or the environment according to current legislation.

**15.2 Chemical safety assessment**

Not required. No data available.

**Section 16: Other Information**

|  |  |
| --- | --- |
| Disclaimer: | The information and recommendations contained herein are basedupon tests believed to be reliable. However, Oxford Immunotec Limited does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage maybe required. Oxford Immunotec Limited assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. |

T-SPOT is a registered trademark of Oxford Immunotec Ltd.

The Oxford Immunotec logo is a registered trademark of Oxford Immunotec Ltd.

© 2022 Oxford Immunotec. All rights reserved.

