**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 | 77-86-1  1185-53-1 | 201-064-4  214-684-5 |
| 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-one  and  2-methyl-4-isothiazol-3-one | 26172-55-4  2682-20-4 | 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 appropriate  international, national, state and local laws and regulations. |
| Contaminated packaging: | Waste disposal must be in accordance with appropriate  international, 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**

|  |  |
| --- | --- |
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