

Safety Data Sheet Revision date: 15 May 2017

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

1.1 Product identifiers

Product Name: T-SPOT.TB

Product Number: TB.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: An *in vitro* diagnostic test intended for use as an aid in the diagnosis of tuberculosis infection.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: Oxford Immunotec Limited
94C Innovation Drive
Milton Park
Abingdon
Oxfordshire
OX14 4RZ
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 (07:00-17:30)

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

2.3 Other hazards

None

Section 3: Composition/information on Components

Microtitre Plate (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, 25mL 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

Congugate Reagent (CR.300)

1 Vial, 50µL volume

Components	Weight %	CAS Number	EINECS-No.
Tris Buffer	1.4	77-86-1	201-064-4
		1185-53-1	214-684-5
MgCl ₂	0.01	7786-30-3	232-094-6
ZnCl ₂	0.001	7646-85-7	231-592-0
Kathon CG	0.15	55965-84-9	Unlisted

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
Kathon CG	55965-84-9	0.15%	
5-chloro-2-methyl-4-isothiazol-3-one	26172-55-4	0.000003%	
and 2-methyl-4-isothiazol-3-one	2682-20-4	0.000003%	

Positive Control (CP.300)

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

Components	Weight %	CAS Number	EINECS-No.
Phytohaemagglutinin	0.0015	9008-97-3	232-718-7
PBS	30		
AIM V	70		

Panel A (PA.300)

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

Components	Weight %	CAS Number	EINECS-No.
17x peptides	0.03 each		
DMSO	2.8	67-68-5	200-664-3
AIM V	97.2		

Panel B (PB.300)

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

Components	Weight %	CAS Number	EINECS-No.
18x peptides	0.03 each		
DMSO	2.8	67-68-5	200-664-3
AIM V	97.2		

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 Panel A (PA.300)

Appearance: Orange/pink liquid
pH: 7.6

9.5 Panel B (PB.300)

Appearance: Orange/pink liquid
pH: 7.7

Section 10: Stability and Reactivity

- 10.1 Reactivity** No data available
- 10.2 Chemical stability** 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

Revisions:	Update in line with REACH/CLP/GHS regulations
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