

MATERIAL SAFETY DATA SHEET

In compliance with 2006/1907/EG

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF COMPANY/UNDERTAKING

1.1 Product identifiers

Product name: TPS® ELISA
 Catalogue Number: 10-212
 Brand: IDL Biotech

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses: TPS® ELISA is an in vitro diagnostic assay intended for quantitative determination of cytokeratin 18 in serum during cancer therapy monitoring and patient follow-up. Performance characteristics are well defined for patients with epithelial cancers, e.g. breast, prostate and ovarian cancer.

1.3 Details of the supplier of the safety data sheet

Company: IDL Biotech
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1.4 Emergency telephone number

Emergency Phone: 112

2. HAZARDS IDENTIFICATION

2.1 Classification of substances and mixtures

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008/EC
 This substance is not classified as dangerous according to Directive 67/548/EC

2.2 Label elements

The product does not need to be labelled in accordance with EC directives.

2.3 Other hazards

Component number	Component Name	Potential Hazard	Applicable Risk (R) and Safety (S) phrases according to EC directives*
1.	TPS® ELISA Coated Microstrips	N/A	N/A
2.	TPS® ELISA HRP Conjugate	Splashes on skin, eyes and ingestion may cause irritation. May be harmful if swallowed. May be harmful if inhaled. Material of animal origin: should be considered as potentially infectious	N/A
3.	TPS® ELISA Diluent (Standard 0 U/l)	Splashes on skin, eyes and ingestion may cause irritation. May be harmful if swallowed. Material of animal origin: should be considered as potentially infectious	N/A
4.	TPS® ELISA Standard 30 U/l Standard 150 U/l Standard 500 U/l Standard 1200 U/l	Splashes on skin, eyes and ingestion may cause irritation. May be harmful if swallowed. Material of animal origin: should be considered as potentially infectious	N/A
5.	TPS® ELISA Control Low Control High	Splashes on skin, eyes and ingestion may cause irritation. May be harmful if swallowed. Material of animal origin: should be considered as potentially infectious	N/A
6.	Wash Tablet	Splashes on skin, eyes and ingestion may cause irritation. May be harmful if swallowed.	N/A
7.	TMB Substrate	Splashes on skin, eyes and ingestion may cause irritation. May be harmful if swallowed. May be harmful if inhaled. May cause respiratory tract irritation.	N/A
8.	Stop Solution	Splashes on skin, eyes and ingestion may cause irritation. May be harmful if swallowed. May be harmful if inhaled. May cause respiratory tract irritation.	N/A
9.	Sealing Tape	N/A	N/A

*) Hazardous components are in low concentration.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

	Component Name	Ingredient	Concentration	CAS#	EC#	Classification (pure ingredient) Regulation (EC) No 1272/2008/EC	Classification (pure ingredient) Directive 67/548/EC
2 3 4 5	TPS® ELISA HRP Conjugate TPS® ELISA Diluent (Standard 0 U/l) TPS® ELISA Standard 30/150/500/2600 U/l TPS® ELISA Control High/Low	Animal originating protein stabilizers	< 10 %	-	-	N/A	N/A
8	Stop Solution	Sulphuric acid	4.9% (0.5M)	7664-93-97	231-639-5	Skin Corr. 1A; H314	C; R35
2 3 4 5	TPS® ELISA HRP Conjugate TPS® ELISA Diluent (Standard 0 U/l) TPS® ELISA Standard 30/150/500/2600 U/l TPS® ELISA Control High/Low	Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	≤ 0.01 %	55965-84-9	613-167-00-5	Acute Tox. 3; Skin Corr. 1B; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1; H301, H311, H314, H317, H331, H410	T, N; R23/24/25 R34, R43, R50/53
7	TMB Substrate	3,3',5,5'-Tetramethyl-benzidine (non-carcinogenic analog of benzidine)	< 0.05 %	54827-17-7	259-364-6	Skin Irr. 2; Eye Irr. 2; Spec. Targ. Organ Tox. Single Exp 3; H315, H319, H335	Xi; R36/37/38
2	TPS® ELISA HRP Conjugate	Oxidizing agent	< 0.005 %	-	-	N/A	R32

For full text of the H-Statements and R-Phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Remove contaminated clothing. Wash well with mild soap and plenty of water. If skin is broken or material gets into open wound, consult a physician.

In case of eye contact

Immediately flush eyes with plenty of water for at least 15 minutes, remove contact lenses if any. Consult a physician.

If swallowed

Flush mouth with plenty of water (do not swallow). Drink large amounts of water. Never give anything to an unconscious person. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical, and toxicological properties have not been investigated.

4.3 Indication of any immediate medical attention and special treatment

No data available

5. FIRE-FIGHTING MEASURES

5.1 Extinguish media

Suitable extinguish media

Powder, water, carbon dioxide or dry sand.

5.2 Special hazards arising from the substances or mixtures

Hazardous combustion products

The product is not combustible but may decompose in the heat of a fire to produce toxic, corrosive or irritating vapours inter alia sulphurous gases (SO_x).

Unusual Fire & Explosion Hazards

Contact with metals may form hydrogen gas which is flammable and can result in explosion.

5.3 Advice for fire-fighters

Self-contained breathing apparatus and protective clothing to avoid all contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapour mist or dust.

6.2 Environmental precautions

Prevent soil and water pollution. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Absorb spills with absorbent material. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For personal protective equipment see section 8. For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Use personal protective equipment. Do not eat, drink, smoke or apply cosmetics.

7.2 Conditions for safe storage, including any incompatibilities

Store in well closed original container at 2-8°C.

7.3 Specific end uses

In vitro diagnostic determination of cytokeratin 18 in serum during cancer therapy, monitoring and patient follow-up. Performance characteristics are well defined for patients with epithelial cancers, e.g. breast, prostate and ovarian cancer.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

not applicable

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Wash and dry hands.
The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection

Use impervious clothing for example a laboratory coat.

Respiratory protection

Respiratory protection not required. For nuisance exposures use type OV/AG (US) or type ABEK (EU EN 14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Component	1 TPS® ELISA Coated Microstrips	2 TPS® ELISA HRP Conjugate	3-4 TPS® ELISA Diluent and Standards	5 TPS® ELISA Controls	6 Wash- tablet	7 TMB Substrate	8 Stop Solution	9 Sealing tape
Appearance	Solid (Microstrips) Clear	Liquid Blue	Liquid Yellow	Liquid Yellow	Solid (Tablet) White	Liquid Clear to light yellow	Liquid Clear	Solid (tape) Clear
Odour	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless	Odourless
Odour Threshold	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
pH	N/A	7.5	7.5	7.5	7.4	3.55 ± 0.20	≤ 1	N/A
Melting point/ Freezing point	N/A	~ 0°C	~ 0°C	~ 0°C	N/A	~ 0°C	~ 0°C	N/A
Initial boiling point	N/A	~ 100°C	~ 100°C	~ 100°C	N/A	~ 100°C	~ 100°C	N/A
Flashpoint	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Evaporation rate	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Flammability (solid gas)	N/A	N/A	N/A	N/A	N/A	Not flammable	N/A	N/A
Upper/lower flammability or explosive limits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Vapour pressure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Vapour density	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Relative density	N/A	N/A	N/A	N/A	N/A	N/A	1.03 – 1.04 at 20°C	N/A
Water solubility	N/A	Soluble	Soluble	Soluble	Soluble	Soluble	Soluble	N/A
Partition coefficient: n- octanol/water	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Auto ignition temperature	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Decomposition temperature	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Viscosity	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Explosive properties	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Oxidizing properties	N/A	N/A	N/A	N/A	N/A	Not an oxidizer	Does not meet the criteria for oxidizing	N/A

9.2 Other information

No other data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

Stop Solution

The product is a dilute solution but can produce reaction characteristic of acids

Other Components

No data available

10.2 Chemical stability

Stable until expiry date stated on label if stored under specified conditions.

10.3 Possibility of hazardous reactions

Stop Solution

May react vigorously or exothermically. Hydrogen may be produced on reaction with metals. Hydrogen sulphide may be produced on reaction with sulphide compounds. Reactions in a sealed container may result in pressure build up with possible rupture of the container.

Other Components

No data available

10.4 Conditions to avoid

Avoid heat, direct sunlight and moisture. Avoid storage in freezing conditions. Avoid storage in an unstable manner or in a situation that would result in exposure to the product. Avoid contact with any incompatible materials.

10.5 Incompatible materials**TPS® ELISA HRP Conjugate**

Acids

TMB Substrate

Strong acids, strong oxidising agents and metals

Stop Solution

Alkali metals, metals, alkali earth metals, strong oxidising agents and sulphides cyanides amines

Other Components

No data available

10.6 Hazardous decomposition products**TMB Substrate**

Toxic fumes of carbon oxides (CO, CO₂) and nitrogen oxide

Stop Solution

None under normal conditions

Other Components

No data available

11. TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****Acute toxicity**

No data available but mixtures are not classified according to EU regulations

Skin corrosion/irritation

No data available but mixtures are not classified according to EU regulations

Serious eye damage/eye irritation

No data available but mixtures are not classified according to EU regulations

Respiratory or skin sensation

No data available but mixtures are not classified according to EU regulations

Germ cell mutagenicity

No data available

Carcinogenicity

No data available but mixtures are not classified according to EU regulations

Stop Solution contains 0.5 M Sulphurous acid. The International Agency for Research on Cancer (IARC) has determined that occupational exposure to strong-inorganic-acid mists containing sulfuric acid is carcinogenic to humans (group 1).

Reproductive toxicity

No data available

Specific target organ toxicity -single exposure

No data available but mixtures are not classified according to EU regulations

Specific target organ toxicity repeated exposure

No data available but mixtures are not classified according to EU regulations

Aspiration hazard

No data available

General information

Splashes on skin, eyes and ingestion may cause irritation. May cause irritation, nausea and vomiting if swallowed. May cause respiratory tract irritation if inhaled.

12.1 Toxicity

12.2 Persistence and degradability

12.3 Bioaccumulative potential

12.4 Mobility in soil

12.5 Result of PBT and vPvB assessment

12.6 Other adverse effects

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

14. TRANSPORT INFORMATION

14.1 UN number

IATA: -

14.2 UN proper shipping name

IATA: Not dangerous goods

14.3 Transport hazard class(es)

IATA: -

14.4 Packaging group

IATA: -

14.5 Environmental hazards

IATA: no

14.6 Special precautions for user

15. REGULATORY INFORMATION AND CONSIDERATIONS

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

No single component contains a hazardous ingredient in an amount that requires identification and labelling.

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

15.2 Chemical Safety Assessment

Chemical safety
No data available

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 3.

Acute Tox. 3	Acute toxicity (Category 3)
Aquatic Acute 1	Acute aquatic (Category toxicity 1)
Aquatic Chronic 1	Chronic aquatic (Category toxicity 1)
Eye Irr. 2;	Eye irritation (Category 2)
Skin Corr. 1B	Skin corrosion (Category 1B)
Skin Irr. 2	Skin irritation (Category 2)
Skin Sens. 1	Skin sensitization (Category 1)
Spec. Targ. Organ Tox. Single Exp 3	Specific target organ toxicity – single exposure (Category 3)
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation
H331	Toxic if inhaled.
H332	Harmful if inhaled.
H335	May cause respiratory irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects

Full text of R-phrases referred to under sections 3

C	
N	Dangerous for the environment
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed
R32	Contact with acids liberates very toxic gas
R34	Causes burns.
R35	Causes severe burns.
R/36/37/38	Irritating to eyes, respiratory system and skin
R43	May cause sensitization by skin contact.
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R53	May cause long-term adverse effects in the aquatic environment.
T	Toxic
Xi	Irritant

This product is designed for use by professionals and for in vitro diagnostics use only.

All material from animal origin has been collected from healthy animals.

Bovine components originate from countries where BSE has not been reported.

THE INFORMATION PROVIDED IN THIS MSDS IS CORRECT TO THE BEST OF OUR KNOWLEDGE, INFORMATION AND BELIEF AT THE DATE OF ITS PUBLICATION. THE USER SHOULD DETERMINE THE SUITABILITY OF THIS INFORMATION FOR THE INTENDED USE OF THE PRODUCT AND ADOPT APPROPRIATE SAFETY PRECAUTIONS. IDL BIOTECH AB SHALL NOT BE LIABLE OR OTHERWISE RESPONSIBLE IN ANY WAY FOR ANY DAMAGE RESULTING FROM HANDLING OR FROM CONTACT WITH THE ABOVE PRODUCT. THE USER IS ALSO RESPONSIBLE FOR OBSERVING ANY LAWS AND APPLICABLE GUIDELINES.

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