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: UBC®II ELISA
Catalogue Number: 10-030
Brand: IDL Biotech

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

Identified uses: UBC® II ELISA is a one step in vitro diagnostic assay for the quantitative determination of cytokeratin 8 and 18 in urine. The assay is a sensitive indicator of tumor cell activity and is useful in the management of patients with urine bladder cancer of epithelial origin.

1.3 Details of the supplier of the safety data sheet

Company: IDL Biotech
Karlsbodavägen 39
P.O. Box 111 51
SE-161 11 Bromma, SWEDEN

Telephone: +46 8 799 67 50
Fax: +46 8 799 93 20
E-mail address: idlbiotech@idl.se
Homepage: www.idl.se

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.	UBC® II ELISA Coated Microstrips	N/A	N/A
2.	UBC® II 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.	UBC® II (Standard 0 µg/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.	UBC® II ELISA Standard 15 µg/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.	UBC® II 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.	Urin Diluent	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*
7.	Wash Tablet	Splashes on skin, eyes and ingestion may cause irritation. May be harmful if swallowed.	N/A*
8.	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*
9.	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*
10.	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#	Classifiaction (pure ingredient) Regulation (EC) No 1272/2008/EC	Classifiaction (pure ingredient) Directive 67/548/EC
2 3 4 5 6	UBC® II ELISA HRP Conjugate UBC® II Diluent (Standard 0 µg/l) UBC® II ELISA Standard 15 µg/l UBC® II ELISA Control High/Low Urine Diluent	Animal originating protein stabilizers	< 10 %	-	-	N/A	N/A
9	Stop Solution	Sulphuric acid	4.9% (0.5M)	7664-93-97	231-639-5	Skin Corr. 1A; H314	C; R35
2 3 4 5 6	UBC® II ELISA HRP Conjugate UBC® II Diluent (Standard 0 µg/l) UBC® II ELISA Standard 15 µg/l UBC® II ELISA Control High/Low Urine Diluent	Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Metyl-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
8	TMB Substrate	3,3',5,5' -Tetrametyl-benzidine (non-caracino-genic 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; R/36/37/38

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 (SOx).

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
Invitro diagnostic determination of cytoceratin 8 and 18 in urine. The assay is a sensitive indicator of tumor cell activity and is useful in the management of patients with urine bladder cancer of epithelial origin.

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 UBC®II ELISA Coated Microstrips	2 UBC®II ELISA HRP Conjugate	3–4 UBC®II ELISA Diluent and Standard	5 UBC®II ELISA Controls	6 Urine Diluent	7 Wash-tablet	8 TMB Substrate	9 Stop Solution	10 Sealing tape
Appearance	Solid (Microstrips) Clear	Liquid Blue	Liquid Clear to light yellow	Solid White to light yellow	Liquid White to light yellow	Solid (Tablet) White	Liquid Clear to light yellow	Liquid Clear	Solid (tape) Clear
Odour	Odourless	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	N/A
pH	N/A	7.5	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	N/A	~ 0°C	N/A	~ 0°C	~ 0°C	N/A
Initial boiling point	N/A	~ 100°C	~ 100°C	N/A	~ 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	N/A
Evaporation rate	N/A	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	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	N/A
Vapour pressure	N/A	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	N/A
Relative density	N/A	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	Soluble	N/A
Partition coefficient: n-octanol/water	N/A	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	N/A
Decomposition temperature	N/A	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	N/A
Explosive properties	N/A	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	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

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, CO_2) and nitrogen oxide

Stop Solution
None under normal conditions

Other Components
No data available

11. TOXILOGICAL 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. ECOLOGICAL INFORMATION

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

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

12.5 Result of PBT and vPvB assessment
Not classified as PBT/vPvB by current EU criteria

12.6 Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
All kit components and tested specimen should be considered as biohazard/infectious and should be disposed of in accordance with federal, state and local environmental regulations.

14. TRANSPORT INFORMATION

14.1 UN number
ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name
ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

14.3 Transport hazard class(es)
ADR/RID: - IMDG: - IATA: -

14.4 Packaging group
ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards
ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user
No data available

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
No data available

15.2 Chemical Safety Assessment
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
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 fore 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.

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