



/ **77 ELEKTRONIKA KFT.**
H-1116 Budapest, Fehérvári út 98.
/ Telefon +36 1 206 1480
/ **Web: E77.HU**

For submission at the competent

Authorities of Republic of Moldova

Letter of Authorization

Whereas, **77 Elektronika Kft** (based at Fehérvári út 98, 1116 – Budapest (Hungary) as manufacturer of Urilyzer® Cell (Urine Microscopy Analyzer) and Urilyzer® Cell Cuvettes (Cuvette for Urine Microscopy Analyzer) do hereby declare that

Sanmedico SRL, str. Petricani 88/1, 0259 Chisinau - Republic of Moldova

is authorized to register, import, promote sell and support the above-mentioned products under the trademark "Urilyzer®" non-exclusively within the territory of Republic of Moldova as a Distributor. We authorize **Sanmedico SRL** to overtake the procedures regarding the registration of the mentioned products at the Authorities of Republic of Moldova. **Sanmedico SRL** is authorized to participate in tenders only in the territory of Republic of Moldova.

Analyticon Biotechnologies GmbH (based at Am Muehlenberg 10, 35104 Lichtenfels (Germany) as distributor of 77 Elektronika Kft is the owner of the trademark "Urilyzer®". 77 Elektronika Kft confirms, that Analyticon Biotechnologies GmbH is the brand owner of the above-mentioned products.

This Letter of Authorization is valid until 31.12.2023. It could be elongated by 77 Elektronika Kft for another period in accordance with **Sanmedico SRL** Cancellation must be in writing with a cancellation period of 3 Months for each party.

For and on behalf of 77 Elektronika Kft

Signed on 17th July 2023, Budapest, Hungary

Sándor Zettwitz

managing director

77 Elektronika Műszeripari Kft.
H-1116 Budapest,
Fehérvári út 98.
23.

 / CÉGJEGYZÉK SZÁMA: 01 09 061328 / ALAPÍTVÁ: 1986 / BBRT 10102093 – 01196703 - 00000005



Management
Systems
ISO 9001
ISO 13485
ISO 14001
www.tuv.com

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1006099-1

Organization: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

Scope: Design and development, production, distribution, installation and servicing of blood glucose measuring systems, urine analyzers and rapid test readers, including related consumables.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 93389457-30
Effective date: 2022-11-18
Expiry date: 2025-11-17
Issue date: 2022-11-09



Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1006099-1

Organization: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary	Design and development, production, distribution, installation and servicing.
/02	77 Elektronika Műszeripari Kft. Telephely Sztregova utca 1 1116 Budapest Hungary	Manufacture and warehouse of blood glucose measuring systems, urine analyzers, related consumables and parts. Manufacturing of SMT technology.

Report No.: 93389457-30
Effective date: 2022-11-18
Expiry date: 2025-11-17
Issue date: 2022-11-09

A blue ink signature is written over a circular blue stamp. The stamp contains the TÜVRheinland logo and the text "TÜVRheinland LGA Products GmbH" and "Zertifizierungsstelle".

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany





EU-DECLARATION OF CONFORMITY

Manufacturer name:	77 Elektronika Műszeripari Kft.
Address:	Fehérvári út 98., H-1116 Budapest
SRN number:	HU-MF-000004266

Product(s) name:	Urilyzer Cell Cuvettes
Reference number:	ULC001
Basic UDI-DI:	59973457CUV9W
GMDN / EMDN	61032 / W02010785
Intended purpose of the device:	Urilyzer Cell Cuvettes are disposable, single use polycarbonate specimen receptacles used to analyse uncentrifuged, human urine samples with Urilyzer Cell urine sediment analysers. It is intended for professional, laboratory use. It is intended for in vitro diagnostic use.
Classification:	A class

The manufacturer declares under its sole responsibility that the above-mentioned product complies with the requirements of the following legislation (s):

Applicable legalisations:	Regulation (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices
----------------------------------	---

Notified Body name:	N/A
Notified Body address:	N/A
Notified Body Identification Number:	N/A
Conformity assessment procedure:	N/A
EC Certificate of conformity's type, number and validity:	N/A

Budapest, 25.05.2022.

Oliver Babinszki
Quality and Environmental Management Director

77 Elektronika Műszeripari Kft.
1116 Budapest, Fehérvári út 98.
Adószám: 10229064-2-44
BBRT: 10102093-01196703-00000005
36.



/ 77 ELEKTRONIKA KFT.

H-11116 Budapest, Fehérvári út 98.

/ Telefon: +36 1 206 1480

/ Web: E77.HU

Declaration of identity

Urilyzer Cell instrument is a commercial variant of the UriSed mini instrument, which distributes exclusively by Analyticon Biotechnologies GmbH. Urilyzer Cell can perform measurement with Urilyzer Cell Cuvettes.

The two instruments (Urilyzer Cell and UriSed mini) are identical in almost every element:

- Measurement process: The user fills the sample to be tested into disposable cuvettes. After a short centrifugation process, the microscopic optical system of the instrument takes images of the cuvette, which are evaluated by the software running on the built-in computer.
- Optical system: Urilyzer Cell uses the same optical system for imaging, including camera, microscope, objective and illumination.
- Evaluation algorithm: Both devices use the same evaluation module to recognize the same type of urine sediment cells.
- Software: In addition to the evaluation algorithm, the entire software system is the same for both devices, only the logo in the software is different, which in the case of Urilyzer Cell is the Analyticon Biotechnologies GmbH logo.
- Cuvette: Both systems use the same cuvette to test the sample.

The only differences between the two devices are:

- The logo on the instrument
- The logo in the software
- The cuvette sleeve holder, in which the cuvette sleeves can be placed. The cuvettes are inserted into the instrument in a cuvette sleeve. This sleeve has ribs outside that prevent UriSed cuvettes from being used with the Urilyzer Cell.

Urilyzer Cell Cuvettes are the commercial variant of UriSed cuvettes.

Urilyzer Cell Cuvettes and UriSed cuvettes are completely identical, they differ only in the sleeve as described above, but this does not result in any difference in the cuvette itself.

Oliver Babinszki
Quality and Environmental Management Director

Urilyzer Cell Cuvettes

REF

ULC001

Instructions for use

Intended use:

Urilyzer Cell Cuvettes are disposable, single use polycarbonate specimen receptacles used to analyse uncentrifuged, human urine samples with Urilyzer Cell urine sediment analysers. It is intended for professional, laboratory use. It is intended for in vitro diagnostic use.

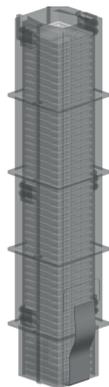
Test principle:

Urilyzer Cell Cuvettes are specimen receptacles allowing for microscopic analysis of urine samples.

Materials not provided:

- Urilyzer Cell urine sediment analyzer
- General laboratory equipment

Using cuvettes:



1 Place the cuvette holder in your analyzer

2 Remove the closing tape of the cuvette holder

Environmental Conditions

Storage temperature	0 – 45°C
Transportation temperature	-25°C – 60°C
Transportation humidity	20 – 80 %
Operation temperature	5°C – 40°C
Operational humidity	20 – 80 %

Warnings and cautions

- Do not store cuvettes in direct sunlight
- Do not remove closing tape from the cuvette holder before installing in your analyzer
- Do not remove partially full cuvette holders from your analyzer
- Each cuvette is single use, never perform a test with previously used cuvette
- Since urine is a fluid of human origin, it may be infectious and may bear the possibility of biological risks
- Handle used Urilyzer Cell Cuvettes and urine contaminants with care
- Dispose of waste according to accepted laboratory instructions and procedures
- Use cuvettes before expiration date

 Check your analysers instructions for use for details on specimen collection, potential preparatory steps, result calculation, analytical and performance characteristics, interferences, limitations, quality control procedures, specific warnings and cautions

Incident reporting

Inform your Analyticon Biotechnologies service representative and your local competent authority about any serious incidents which may occur when using this product.

Symbols:

	Unique Device Identifier
	In vitro diagnostic medical device
	Catalogue Number
	Lot Number
	The CE mark identifies that the product complies with the applicable directives of the European Union
	Use by
	Temperature Limitation
	Manufacturer
	Keep away from sunlight
	Consult instructions for use
	Humidity limitation
	Caution
	600 Contents sufficient for 600 tests
	Do NOT Reuse
	Country of origin and manufacturing date
	Distributed by

Version history

Version	Date	Changes
1	2022.04.12.	First release

CE

 Manufacturer:

77 Elektronika Kft.
98. Fehérvári út, 1116 Budapest
HUNGARY
www.en.e77.hu
sales@e77.hu
Tel: + 36 1 206 - 1480
Fax: + 36 1 206 - 1481

 Distributed by:

Analyticon Biotechnologies GmbH
Am Muehlenberg 10
35104 Lichtenfels, Germany
info@analyticon-diagnostics.com
www.analyticon-diagnostics.com

**For submission at the competent
Authorities of the Republic of Moldova**



Letter of Authorization

WHEREAS, **Analyticon Biotechnologies GmbH**, who is an established, and well-known manufacturer and producer of Medical Diagnostics having production facilities at 35104 Lichtenfels (Germany), Am Muehlenberg 10, do hereby declare that

Sanmedico SRL

A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova

Tel: +373 60 15-57-88

E-Mail: sanmedico.office@gmail.com

is authorized to register, import, promote and sell our urinalysis and hematology products non-exclusively within the territory of the Republic of Moldova as a Distributor for our products. We authorize Sanmedico SRL to overtake the procedures regarding the registration of the mentioned products and the Renewal of expiring Licenses for Sale of our product range of these In-Vitro-Diagnostic products at the Authorities of the Republic of Moldova. Sanmedico SRL is authorized to participate in tenders only in the territory of the Republic of Moldova. This Letter of Authorization is valid for three (3) years from the date of issue. It could be elongated from Analyticon Biotechnologies AG for another period in accordance with Sanmedico SRL. Cancellation must be in writing with a cancellation period of 3 Months for each party.

The construction of this agreement, validity and performance of this agreement and all subsequent agreements shall be exclusively governed by the laws of Germany. This agreement shall be interpreted under German Law. The laws of the Federal Republic of Germany are legally binding; this excludes the validity of the UN purchasing laws, particularly the United Nations treaty on contracts regarding the international sale of moveable property. This is also valid should the DISTRIBUTOR not be of German nationality or his head office be situated outside Germany. The parties submit to the exclusive jurisdiction of the District Courts at Korbach, Postal Code D-34497, Germany / the regional court of the city of Kassel, Germany. This Authorisation letter will replace all other existing Authorisation letters between the parties.

For and on behalf of Analyticon Biotechnologies GmbH
Signed on 14th June 2023, at Lichtenfels (Germany)

Dennis Kasper
Business Area Manager Europe (East) & Africa
Analyticon Biotechnologies GmbH

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Analyticon Biotechnologies GmbH

Scope of certification:

Development, production and distribution of in-vitro diagnostics from the field of urine diagnostics for professional and near-patient applications

Distribution, service and installation of in-vitro-diagnostic analyzers from the field of urine diagnostics.

Distribution of in-vitro diagnostic devices from the field of hematology

Distribution and service of in-vitro-diagnostic analyzers from the field of hematology

Certified location:

Am Mühlberg 10, 35104 Lichtenfels, Germany
(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 51519-R1-00.

Certificate registration no.: 51519-14-02_EN

Certificate valid from: 2023-03-06

Validity of previous certificate: 2023-03-05

Certificate valid to: 2025-01-10


Karin Leicht



DEKRA Certification GmbH, Stuttgart, 2023-03-06



Annex to the Certificate No. 51519-14-02

valid from 2023-03-06 to 2025-01-10

The following locations/companies belong to the certificate above:

	Headquarters	Scope of certification
	Analyticon Biotechnologies GmbH Am Mühlberg 10 35104 Lichtenfels Germany	see page 1
	at the following locations/at the companies at the following locations	Scopes of certification
1.	Am Teichsberg 10 Lichtenfels-Sachsenberg Germany	Reception, shipping and storage of raw materials, semi-finished goods, finished goods and analyzers from the fields of urine diagnostics and hematology.



Karin Leicht

Karin Leicht
DEKRA Certification GmbH, Stuttgart, 2023-03-06

CombiScreen® Urine Control



CombiScreen® Dip Check Art.-No. 93010

Ready-to-use dipper control

2 x 15 ml (Level 1 + Level 2)

Open vial stability (at 2–8 °C) of 75 days or 20 determinations (whichever occurs first)

CombiScreen® Drop Check Art.-No. 93015

Ready-to-use dropper control

2 x 5 ml (Level 1 + Level 2)

Open vial stability of 18 months (2–8 °C) or 30 days (20–25 °C)

Features:

- Based on human standard material
- Suitable for use in POC testing
- Shatter proof vials (polystyrene)
- 2D-barcode on tube vial for direct entry of lot number and target values into Urilyzer® 100 Pro and Urilyzer® 500 Pro instruments
- Target values for CombiScreen® test strips as well as other test strip brands
- Parameters: Bilirubin, Urobilinogen, Ketones, Glucose, Protein, Blood, pH, Nitrite, Leukocytes, Specific Gravity, Creatinine, Microalbumin and hCG
- Qualitative hCG values

CombiScreen® urine controls cover a wide range of analytes, including pregnancy markers and Microalbumin. The controls are designed for use in manual and automated methods, to monitor the performance of a variety of urine test strips.

Analyticon Biotechnologies GmbH
Am Muehlenberg 10
35104 Lichtenfels - Germany
Phone: +49 6454 7991-0
info@analyticon-diagnostics.com
www.analyticon-diagnostics.com

agile - affordable - accurate

Urilyzer[®] 100 Pro



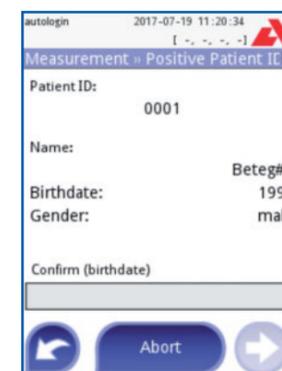
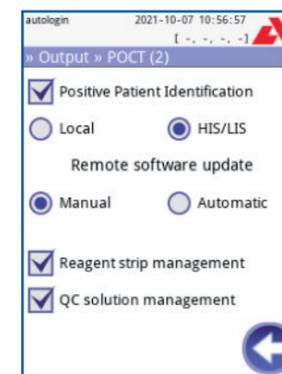
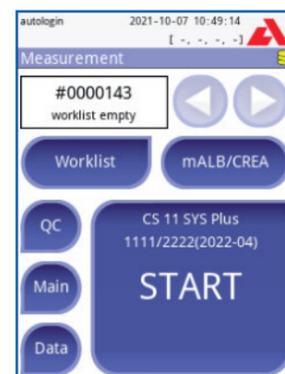
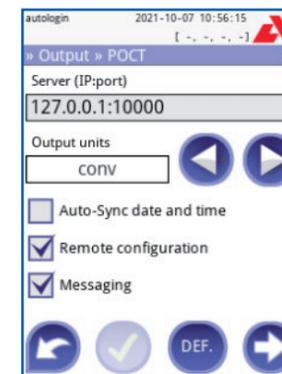
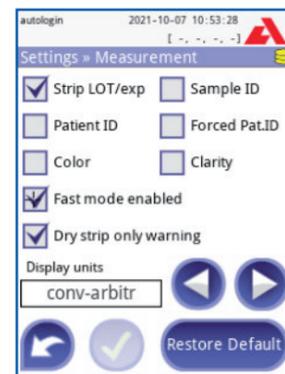
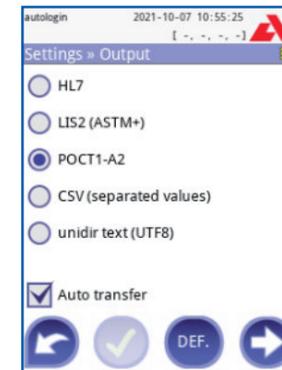
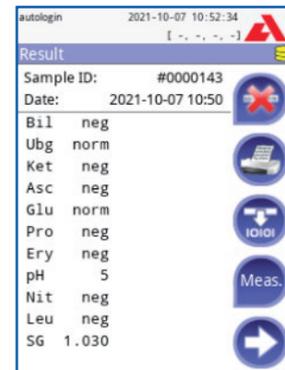
**A new way
in urinalysis**



- Easy-to-use
- Smart and safe operation
- Extended connectivity capabilities
- POCT-features

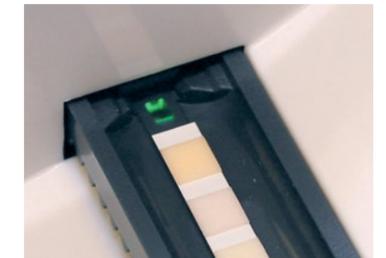
Easy-to-use

- A Start-Up Wizard leads the operator through the user-defined settings upon first start of the device.
- Automatic start of the measurement after placing the urine test strip allows hygienic and clean operation of the analyzer
- Positive results, reminders and warnings are shown in color (e.g. red or yellow) and can be easily identified
- The user interface offers a high level of customization with flexible testing and reporting options



Connectivity capabilities

- Data can be transferred via serial connection or Ethernet
- A variety of interfaces for connecting external barcode scanner and/or keyboard (USB or PS2)
- Implemented protocols: HL7, LIS2 (ASTM+), POCT1-A2



CombiScreen® DIP Check
Catalog No. 93010 2 x 15 mL Lot No. Y 686 Expiry 2020/05

Analyte	Visual		Instrumental (Analyticon CombiScan® / Urilizer®)	
	Level 1	Level 2	Level 1	Level 2
Ascorbic Acid	Negative	Negative	Negative - 20 mg/dl Negative - 1+	Negative - 20 mg/dl Negative - 1+
Bilirubin	Negative	1+ - 3+	Negative	1+ - 3+ 1+ - 3+ 1+ - 3+
Blood	Negative (*)	10 - 300 Eryul 1+ - 3+	Negative (*)	10 - 300 Eryul 1+ - 3+
Glucose	Normal	50 - 1000 mg/dl 2.8 - 58 mmol/L	Normal	50 - 1000 mg/dl 2.8 - 58 mmol/L 1+ - 3+
Ketones	Negative	(+) - 3+	Negative	10 - 300 mg/dl 0.2 - 30 mmol/L (+) - 3+
Leucocytes	Negative	20 - 500 Leucyl 1+ - 3+	Negative	20 - 500 Leucyl 1+ - 3+
Nitrite	Negative (*)	Positive	Negative (*)	Positive
pH	5 - 6	7 - 9	5 - 7	6 - 9
Protein	Negative	30 - 500 mg/dl	Negative	30 - 500 mg/dl 0.2 - 5.0 g/l 1+ - 3+
Specific Gravity	1.020 - 1.030	1.000 - 1.015	1.015 - 1.030	1.000 - 1.030

Level 1 (L1)



Level 2 (L2)



Instrumental (Analyticon CombiScan® / Urilizer®)

Level 1	Level 2
Negative - 20 mg/dl Negative - 1+	Negative - 20 mg/c Negative - 1+

Smart and safe operation

- Tracking of LOT-No. for urine strips and quality control solutions
- Data management provides multiple filter options
- QC ranges can be entered via QR-Code
- Automated QC analysis with customizable QC test reminders including lockout function
- System allows the allocation of different security levels to individual users

POCT1-A2 features

- Validated for use with Siemens UniPOC™ and POCcelerator™*
- Remote configuration via middleware
- Automated synchronization of date and time via the middleware
- Messaging function allows the POCT datamanager to send messages to addressed operators or instruments
- Positive Patient Identification (PPID)
- Remote software update
- Test strip management
- QC solution management
- Proficiency test feature

* please contact us for other middleware options

Technical Specifications

Type	Semi-automated urine test strip analyzer	
Measurement technology	Reflectance photometer with 4 discrete wavelengths 505, 530, 620, 660 nm	
Parameters	11 Parameter: Bilirubin, Urobilinogen, Ketones, Ascorbic Acid, Glucose, Protein (Albumin), Blood (Hemoglobin), pH, Nitrite, Leucocytes, Specific Gravity 7 Parameter: Ketones, Glucose, Protein (Albumin), Blood (Hemoglobin), Nitrite, Leucocytes, pH 5 Parameter: Glucose, Protein (Albumin), Blood (Hemoglobin), Nitrite, Leucocytes 2 Parameter: Albumin, Creatinine	
Throughput	Up to 50 tests/hour (in normal mode)	Up to 120 tests/hour (in fast mode)
Data storage	Patient database: 3.000 tests	QC database: 1.000 tests
Display	3.5" QVGA touchscreen LCD	
Interfaces	Serial RS232, USB Type A, USB Type B, PS2 (external keyboard, barcode reader), Ethernet	
Dimensions	208 x 290 x 80 mm (WxDxH)	
Weight	1.2 kg	
Power supply	7.5 V DC / 3 A	
Operating environment	Temperature: +15°C to +32°C Relative humidity (non-condensing): 30% to 80% Atmospheric pressure: 70 kPa to 106 kPa	
Printer	Built-in thermal printer	
Barcode reader	External	
Protocols	LIS2 (ASTM+), HL7, POCT1-A2	
Features	<ul style="list-style-type: none"> • Start-Up Wizard upon first usage • Operator Management with advanced system security options • Test strip & QC Management (full traceability via LOT and Expiry entry) • Data Management, Power Management • Autostart of measurement (automatic strip detection) • Automatic printout or transfer of result • Flexible advanced information entry (e.g. sample color and turbidity) • Flexible advanced testing and reporting options (e.g. sediment recommendation flag) 	
Languages	Czech, Danish, English, Finish, French, German, Greek, Hungarian, Italian, Norwegian, Polish, Romanian, Russian, Spanish, Swedish	

Art.-No.: UL0100Pro

Consumables



Urine test strips

CombiScreen® 11SYS PLUS	100/150 strips	94100/94150
CombiScreen® 7SYS PLUS	100/150 strips	94110/94110A
CombiScreen® 5SYS PLUS	100 strips	94109
CombiScreen® 11SYS	100/150 strips	93100/93150
CombiScreen® mALB / CREA	25 strips	94025

Control

CombiScreen® Dip Check	2 x 15 ml	93010
CombiScreen® Drop Check	2 x 5 ml	93015

Pack size

100/150 strips
100/150 strips
100 strips
100/150 strips
25 strips

Art.-No.

94100/94150
94110/94110A
94109
93100/93150
94025



Distributor information



Analyticon Biotechnologies GmbH

Am Muehlenberg 10
 35104 Lichtenfels - Germany
 Phone: +49 6454 7991-0
 info@analyticon-diagnostics.com
 www.analyticon-diagnostics.com

Konformitätserklärung – Urin Diagnostik /
Declaration of Conformity – Urine Diagnostics



Analyticon Biotechnologies GmbH

**Am Mühlenberg 10,
35104 Lichtenfels, Germany**

Wir erklären in alleiniger Verantwortung, dass die Medizinprodukte für die In-vitro-Diagnostik
We declare under our sole responsibility that the in vitro diagnostic medical devices

Bezeichnung und Artikelnummer: siehe Anhang
Description and article number: see annex

mit folgender Klassifizierung nach der Richtlinie über In-Vitro-Diagnostika 98/79/EG
classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC

- Produkt der Liste A, Anhang II / Device of List A, Annex II
- Produkt der Liste B, Anhang II / Device of List B, Annex II
- Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist /
Device for self-testing not listed in Annex II
- Sonstiges Produkt / *Other device*

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.
meet all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

Konformitätsbewertungsverfahren
Conformity assessment procedure

IVD 98/79/EG, Artikel 9 (1) und Anhang III /
IVD 98/79/EC Article 9 (1) and Annex III

EDMA-Code und Registrierungsnummer
EDMS-Code and Registration-No.

siehe Anhang
see annex

Konformitätsbewertungsstelle

nicht erforderlich, die Bewertung wurde in
Eigenverantwortung des Herstellers durchgeführt

Notified Body (if consulted)

*not applicable, evaluation was carried out under
the manufacturer's own responsibility*

Ort, Datum / *Place, date*

Name und Funktion / *Name and function*

Lichtenfels, 18.01.2023


Dr. Jürgen Schmich
(Direktor Qualitätssicherung / Director Quality Assurance)



Analyticon Biotechnologies GmbH
Am Mühlenberg 10,
35104 Lichtenfels, Germany

Anhang zur Konformitätserklärung – Urin Diagnostik /
Declaration of Conformity, Annex – Urine Diagnostics

CombiScreen Urine Controls

Name	REF	EDMS-Code	Reg.-Nr.
CombiScreen® Dip Check	93010	11.50.90.02.00	DE/CA30/00041388
CombiScreen® Drop Check	93015	11.50.90.02.00	DE/CA30/00041388

Konformitätserklärung – Urin Diagnostik /
Declaration of Conformity – Urine Diagnostics



Analyticon Biotechnologies GmbH

**Am Mühlenberg 10,
35104 Lichtenfels, Germany**

Wir erklären in alleiniger Verantwortung, dass die Medizinprodukte für die In-vitro-Diagnostik
We declare under our sole responsibility that the in vitro diagnostic medical devices

Bezeichnung und Artikelnummer: siehe Anhang
Description and article number: see annex

mit folgender Klassifizierung nach der Richtlinie über In-Vitro-Diagnostika 98/79/EG
classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC

- Produkt der Liste A, Anhang II / Device of List A, Annex II
- Produkt der Liste B, Anhang II / Device of List B, Annex II
- Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist /
Device for self-testing not listed in Annex II
- Sonstiges Produkt / *Other device*

allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht, die anwendbar sind.
meet all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

Konformitätsbewertungsverfahren
Conformity assessment procedure

IVD 98/79/EG, Artikel 9 (1) und Anhang III /
IVD 98/79/EC Article 9 (1) and Annex III

EDMA-Code und Registrierungsnummer
EDMS-Code and Registration-No.

siehe Anhang
see annex

Konformitätsbewertungsstelle

nicht erforderlich, die Bewertung wurde in
Eigenverantwortung des Herstellers durchgeführt

Notified Body (if consulted)

*not applicable, evaluation was carried out under
the manufacturer's own responsibility*

Ort, Datum / *Place, date*

Name und Funktion / *Name and function*

Lichtenfels, 18.01.2023


Dr. Jürgen Schmich
(Direktor Qualitätssicherung / Director Quality Assurance)



Test strips visual and semi-automated systems

Name	REF	EDMS-Code	Reg.-Nr.
CombiScreen® 11SYS	93100	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS	93150	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL	93120B	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3	93108A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GAK	93107	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GAK	93107A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GP	93104	11.70.02.02.00	DE/CA30/00017200
CombiScreen® GPK	93105	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94100	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94150	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 11SYS PLUS	94150BC	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 10SL PLUS	94120	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9 PLUS	94115	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9+Leuko PLUS	94250	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 9+Leuko PLUS	94200	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 7SYS PLUS	94110	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 7SYS PLUS	94110A	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5SYS PLUS	94109	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+Leuko PLUS	94517	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+Leuko PLUS	94117	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+N PLUS	94535	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 5+N PLUS	94135	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3 PLUS	94508	11.70.02.02.00	DE/CA30/00017200
CombiScreen® 3 PLUS	94108	11.70.02.02.00	DE/CA30/00017200
CombiScreen® Glu PLUS	94501	11.70.02.02.00	DE/CA30/00017200
CombiScreen® Nitrit PLUS	94506	11.70.02.02.00	DE/CA30/00017200
CombiScreen® mALB / CREA	94025	11.70.02.02.00	DE/CA30/00017200

Authorization Certificate



Vitalie Goreacii

SANMEDICO SRL

This is to certify that the above named general manager has successfully completed the full application and technical training which was specifically prepared and carried out on the Analyticon Biotechnologies GmbH equipment mentioned below on May 22nd to 23rd, 2023

Urilyzer[®] Cell

We hereby state that the general manager is authorized and qualified by Analyticon to do installation, operation, user and technical training, service and maintenance of the equipment listed above.

Analyticon
Biotechnologies GmbH
Customer Support & Trainings



Handwritten signature of Nathalie Mütze in blue ink.

Nathalie Mütze
Manager Customer Support

Handwritten signature of Nils Albrecht in blue ink.

Nils Albrecht
Customer Support

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 1

Revision date: 17.02.2023

Product code: 1R93015

Page 2 of 7

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Rinse mouth immediately and drink plenty of water.

Rinse mouth thoroughly with water.

Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

The product itself does not burn.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

Prevent spread over a wide area (e.g. by containment or oil barriers).

Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up

Other information

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

Take up dust-free and set down dust-free.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Use only in well-ventilated areas.

The floor should be leak tight, jointless and not absorbent.

All work processes must always be designed so that the following is excluded:

Advice on protection against fire and explosion

Usual measures for fire prevention.

When using do not smoke.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 1

Revision date: 17.02.2023

Product code: 1R93015

Page 3 of 7

Wash hands before breaks and after work.

Further information on handling

When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed.

Keep only in the original container in a cool, well-ventilated place.

Further information on storage conditions

2 8

Protect against:

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****8.2. Exposure controls****Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. EN ISO 374

Breakthrough times and swelling properties of the material must be taken into consideration.

Skin protection

Wear suitable protective clothing. Suitable protective clothing:

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Respiratory protection necessary at:

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:

Colour:

Odour: characteristic

Melting point/freezing point:

not determined

Boiling point or initial boiling point and

not determined

boiling range:

Flammability:

not determined

not applicable

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 1

Revision date: 17.02.2023

Product code: 1R93015

Page 4 of 7

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Decomposition temperature:	not determined
Partition coefficient n-octanol/water:	not determined
Vapour pressure:	not determined
Density:	not determined
Relative vapour density:	not determined

9.2. Other information**Information with regard to physical hazard classes****Explosive properties**

The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.

Self-ignition temperature

Solid:	not determined
Gas:	not applicable

Other safety characteristics

Evaporation rate:	not determined
Solid content:	not determined

SECTION 10: Stability and reactivity**10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

May cause decomposition by long-term light influence.

10.5. Incompatible materials

No information available.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

No information available.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Sensitising effects

No information available.

STOT-repeated exposure

No information available.

Specific effects in experiment on an animal

No information available.

Additional information on tests

The mixture is classified as not hazardous according to Directive 1999/45/EC.

11.2. Information on other hazards

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 1

Revision date: 17.02.2023

Product code: 1R93015

Page 5 of 7

Endocrine disrupting properties

No information available.

SECTION 12: Ecological information**12.1. Toxicity**

The product has not been tested.

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. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No data available

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Dispose of waste according to applicable legislation. Dispose of waste according to applicable legislation.

Dispose of waste according to "Kreislaufwirtschafts- und Abfallgesetz (KrW-/AbfG)".

List of Wastes Code - residues/unused products

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - used product

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - contaminated packaging

150106 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); mixed packaging

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information**Land transport (ADR/RID)****14.1. UN number or ID number:**

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 1

Revision date: 17.02.2023

Product code: 1R93015

Page 6 of 7

Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulatory information**

Water hazard class (D): - - non-hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 2,11.

Abbreviations and acronymsADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations. The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing,

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 1

Revision date: 17.02.2023

Product code: 1R93015

Page 7 of 7

transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.

The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 2

Revision date: 17.02.2023

Product code: 2R93015

Page 2 of 7

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Rinse mouth immediately and drink plenty of water.

Rinse mouth thoroughly with water.

Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

The product itself does not burn.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

Prevent spread over a wide area (e.g. by containment or oil barriers).

Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up

Other information

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

Take up dust-free and set down dust-free.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Use only in well-ventilated areas.

The floor should be leak tight, jointless and not absorbent.

All work processes must always be designed so that the following is excluded:

Advice on protection against fire and explosion

Usual measures for fire prevention.

When using do not smoke.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 2

Revision date: 17.02.2023

Product code: 2R93015

Page 3 of 7

Wash hands before breaks and after work.

Further information on handling

When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed.

Keep only in the original container in a cool, well-ventilated place.

Further information on storage conditions

2 8

Protect against:

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****8.2. Exposure controls****Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. EN ISO 374

Breakthrough times and swelling properties of the material must be taken into consideration.

Skin protection

Wear suitable protective clothing. Suitable protective clothing:

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Respiratory protection necessary at:

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:

Colour:

Odour: characteristic

Melting point/freezing point:

not determined

Boiling point or initial boiling point and

not determined

boiling range:

Flammability:

not determined

not applicable

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 2

Revision date: 17.02.2023

Product code: 2R93015

Page 4 of 7

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Decomposition temperature:	not determined
Partition coefficient n-octanol/water:	not determined
Vapour pressure:	not determined
Density:	not determined
Relative vapour density:	not determined

9.2. Other information**Information with regard to physical hazard classes****Explosive properties**

The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.

Self-ignition temperature

Solid:	not determined
Gas:	not applicable

Other safety characteristics

Evaporation rate:	not determined
Solid content:	not determined

SECTION 10: Stability and reactivity**10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

May cause decomposition by long-term light influence.

10.5. Incompatible materials

No information available.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

No information available.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Sensitising effects

No information available.

STOT-repeated exposure

No information available.

Specific effects in experiment on an animal

No information available.

Additional information on tests

The mixture is classified as not hazardous according to Directive 1999/45/EC.

11.2. Information on other hazards

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 2

Revision date: 17.02.2023

Product code: 2R93015

Page 5 of 7

Endocrine disrupting properties

No information available.

SECTION 12: Ecological information**12.1. Toxicity**

The product has not been tested.

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. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

The product has not been tested.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No data available

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Dispose of waste according to applicable legislation. Dispose of waste according to applicable legislation.

Dispose of waste according to "Kreislaufwirtschafts- und Abfallgesetz (KrW-/AbfG)".

List of Wastes Code - residues/unused products

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - used product

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - contaminated packaging

150106 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); mixed packaging

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information**Land transport (ADR/RID)****14.1. UN number or ID number:**

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 2

Revision date: 17.02.2023

Product code: 2R93015

Page 6 of 7

Inland waterways transport (ADN)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number or ID number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulatory information**

Water hazard class (D): - - non-hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 2,11.

Abbreviations and acronymsADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations. The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing,

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® Drop Check Level 2

Revision date: 17.02.2023

Product code: 2R93015

Page 7 of 7

transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.

The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® 11SYS

Revision date: 20.02.2023

Product code: 93150

Page 1 of 6

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

CombiScreen® 11SYS

Product group: Endprodukt / Endproduct

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.3. Details of the supplier of the safety data sheet**

Company name:	Analyticon® Biotechnologies GmbH	
Street:	Am Mühlenberg 10	
Place:	D-35104 Lichtenfels	
Telephone:	+49 (0) 6454/7991-0	Telefax: +49 (0) 6454/7991-30
E-mail:	[REDACTED]	
Contact person:	Zentrale	Telephone: +49 (0) 6454/7991-0
Internet:	[REDACTED]	

1.4. Emergency telephone number: Zentrale: +49 (0) 6454/7991-0

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No 1272/2008**

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Hazardous components**

none (according to Regulation (EC) No 1907/2006 (REACH))

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Rinse mouth thoroughly with water.

Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® 11SYS

Revision date: 20.02.2023

Product code: 93150

Page 2 of 6

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings. The product itself does not burn.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Avoid dust formation.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

Prevent spread over a wide area (e.g. by containment or oil barriers).

Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up

Other information

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Take up dust-free and set down dust-free.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Use only in well-ventilated areas.

The floor should be leak tight, jointless and not absorbent.

All work processes must always be designed so that the following is excluded:

Advice on protection against fire and explosion

Usual measures for fire prevention.

When using do not smoke.

Advice on general occupational hygiene

Take off contaminated clothing. When using do not eat or drink. Wash hands before breaks and after work.

Further information on handling

When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep only in the original container in a cool, well-ventilated place.

Further information on storage conditions

15 25

Protect against:

SECTION 8: Exposure controls/personal protection

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® 11SYS

Revision date: 20.02.2023

Product code: 93150

Page 3 of 6

8.1. Control parameters**Occupational exposure limit values**

CAS No	Name of agent	ppm	mg/m ³	fib/cm ³	Category	Origin
7664-38-2	Orthophosphoric acid	-	1		TWA (8 h)	
		-	2		STEL (15 min)	

8.2. Exposure controls**Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. EN ISO 374

Breakthrough times and swelling properties of the material must be taken into consideration.

Skin protection

Wear suitable protective clothing.

Respiratory protection

Respiratory protection necessary at:

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:

Colour:

Odour: characteristic

Melting point/freezing point:

not determined

Boiling point or initial boiling point and

not determined

boiling range:

Flammability:

not determined

not applicable

Lower explosion limits:

not determined

Upper explosion limits:

not determined

Decomposition temperature:

not determined

pH-Value:

No data available

Water solubility:

The study does not need to be conducted because the substance is known to be insoluble in water.

Solubility in other solvents

Buffer

Partition coefficient n-octanol/water:

not determined

Vapour pressure:

not determined

Density:

not determined

Relative vapour density:

not determined

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® 11SYS

Revision date: 20.02.2023

Product code: 93150

Page 4 of 6

9.2. Other information**Information with regard to physical hazard classes****Explosive properties**

The study does not need to be conducted because there are no chemical groups associated with explosive properties present in the molecule.

Self-ignition temperature

Solid: not determined
Gas: not applicable

Other safety characteristics

Evaporation rate: not determined
Solid content: not determined

SECTION 10: Stability and reactivity**10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

May cause decomposition by long-term light influence.

10.5. Incompatible materials

No information available.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity**

No information available.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

No information available.

Sensitising effects

No information available.

Carcinogenic/mutagenic/toxic effects for reproduction

No information available.

STOT-repeated exposure

No information available.

Specific effects in experiment on an animal

No information available.

Additional information on tests

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

11.2. Information on other hazards**Endocrine disrupting properties**

No information available.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® 11SYS

Revision date: 20.02.2023

Product code: 93150

Page 5 of 6

SECTION 12: Ecological information**12.1. Toxicity**

The product has not been tested.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

The product has not been tested.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Dispose of waste according to "Kreislaufwirtschafts- und Abfallgesetz (KrW-/AbfG)".

Contaminated packaging

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information**Land transport (ADR/RID)****Other applicable information (land transport)**

No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)**Other applicable information (inland waterways transport)**

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)**Other applicable information (marine transport)**

No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)**Other applicable information (air transport)**

No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CombiScreen® 11SYS

Revision date: 20.02.2023

Product code: 93150

Page 6 of 6

not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 75

2004/42/EC (VOC): 0,009 %

National regulatory information

Water hazard class (D): - - non-hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information**Changes**

This data sheet contains changes from the previous version in section(s): 11.

Abbreviations and acronymsADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Skin Corr: Skin corrosion

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)