Liofilchem® Certificate of Analysis

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Conforms

Product	Batch	Expiration date	
Sabouraud Dextrose Agar (Irradiated)	083121052	2022.02.27	
Ref. 10035S			
Treatment	Irradiation Dose (kGy)	Date	
Treatment Certificate No. 240.892	12.5	17.09.2021	
Physical quality control	Specification	Results	
Expected pH-value (25°C)	5.6 ± 0.2	5.6	
Appearance of medium	Slightly opalescent	Conforms	
Colour of medium	Light amber	Conforms	
Microbiological State			
Sampled according to ISO 2859-1, Special Inspection	Level: S-2		
Incubation	Specification	Results	
32.5 ± 2.5°C (after 48 h and 7 days)	No growth	Conforms	

No growth

All units of this batch were checked before packaging.

Microbiological Performance

22.5 ± 2.5°C (after 48 h and 7 days)

Tested according to CLSI M22-A3, EN ISO 11133, Harmonized USP/EP/JP Reference media: Sabouraud Dextrose Agar – batch already validated

Productivity, Method of control: Quantitative

Inoculum: 50-100 CFU

Control strains	Incubation	Expected Results	Specification	Results
Saccharomyces cerevisiae WDCM 00058	Aerobic, $72 \pm 2 \text{ h}$ 22.5 ± 2.5°C	$P_R \! \geq \! 0.7$	Good growth	Conforms
Aspergillus brasiliensis WDCM 00053	Aerobic, 3-5 d $22.5 \pm 2.5^{\circ}$ C	$P_R \! \geq \! 0.7$	Good growth	Conforms
Candida albicans WDCM 00054	Aerobic, $46 \pm 2 \text{ h}$ 22.5 ± 2.5°C	$P_R\!\ge\!0.7$	Good growth	Conforms
Candida albicans ATCC® 10231	Aerobic, 24-48 h 32.5 ± 2.5°C	$P_R\!\ge\!0.7$	Good growth	Conforms

Batch Release

Approved

Date 22.09.2021 Signature

The results reported were obtained at the time of release.

Quality Control
(D. Vitagliano)

Danio Vitagliano



ALLEGATO AL CERTIFICATE OF PROCESSING

Annex to the Certificate of Processing

Att# 240 892 **Data** 17/09/2021 **SO#** 2866155

Sterigenics rif.# 6561/2021

Mandante LIOFILCHEM S.R.L. (6)

Documento di trasporto# 14302 **Del** 14/09/2021 **Colli (quantità):** 1

Dated Dated Colli (quantità): 1

Dated Units (Quantity)

Ricevente LIOFILCHEM S.R.L. (6)

Ship to **PRODUCT ITEM #**LIOF_2346/15_681/14

Cliente LIOFILCHEM S.R.L. (6) Packing List# www_6_77995

Descrizione Prodotto (come dichiarato dal Cliente nella packing list elettronica)

Description of goods (as reported in the electronic packing-list by the Customer)

083121052 083021136		

La merce sopra descritta dal Committente o suo delegato, è stata sottoposta a trattamento mediante esposizione a raggi gamma generate da Cobalto 60 (radiazioni ionizzanti) come riportato nel certificate of processing del WO a cui il presente Report è allegato, utilizzando impianti e procedure di controllo conformi alle norme ISO 9001, ISO 13485, ISO 11137-1.

Sterigenics Italy SpA declina qualsiasi responsabilità derivante da eventuali errori presenti nella Packing-List elettronica compilata dal Cliente o suo delegato.

The goods described above by the Customer or Designee, have been processed using Cobalt -60 gamma rays as reported in the WO specific Certificate of processing to which this Report is annexed, using machinery and control procedures which comply with the requirements of ISO 9001, ISO 13485, EN ISO 11137-1

Sterigenics Italy can accept no liability arising from possible errors in the digital packing-list completed by the Customer or Designee

Ciclo standard:12.5kGyDose Minima:13.2kGyStandard CycleDose Massima:16.6kGy

Dosimetro tipo Red Perspex 4034 Lotto:PY

Red Perspex 4034 Lotto:PY

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