



Product	Batch	Manufacturing date	Expiration date
<b>BioCapt Tryptic Soy Agar + Neutralizers + Pyruvate</b>	060619073	2019/06/06	2020/06/05

Ref. 19103S (79001206)

Gamma Rays Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. 220.764	12,5	2019/07/08

Physical quality control	Specification	Results
Expected pH-value (25°C)	7.3 ± 0.2	7.3
Appearance of medium	Slightly opalescent	Conforms
Colour of medium	Light amber	Conforms
Filling media volume	30 ml ± 1 ml	Conforms
Media Composition	BSE free	Conforms

**Sterility Control- Absence of contamination (before gamma irradiation)**

32.5 ± 2.5 °C aerobic for 7 days	Conforms
22.5 ± 2.5 °C aerobic for 7 days	Conforms

**Microbiological Performance- Growth Promotion Test (after gamma irradiation)**

Tested according to CLSI M22-A3, EN ISO 11133, Harmonized USP/EP/JP  
Reference media: Tryptic Soy Agar

**Productivity, Method of control: Quantitative**

Inoculum: 10-100 CFU

Control strains	Incubation	Expected Results	Recovery	Results
<i>Bacillus subtilis</i> ATCC® 6633	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	102%	Conforms
<i>Escherichia coli</i> ATCC® 8739	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	75%	Conforms
<i>Staphylococcus aureus</i> ATCC® 6538	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	92%	Conforms
<i>Pseudomonas aeruginosa</i> ATCC® 9027	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	84%	Conforms
<i>Candida albicans</i> ATCC® 10231	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	90%	Conforms
<i>Aspergillus brasiliensis</i> ATCC® 16404	Aerobic, 72- 120 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	85%	Conforms

RECOVERY: RESULTS AS CFU ENUMERAION ON TEST BATCH AGAR PLATES x 100/ CFU ENUMERATIONON REFERENCE TESTS.  
REFERENCE MEDIUM FOR RECOVERY TESTS: TSA FOR ALL BACTERIA AND SDA FOR YEAST AND MOLD SPECIES  
ATCC IS REGISTERED TRADE MARK OF AMERICAN TYPE CULTURE COLLECTION

**Batch Release**

Approved

Date

2019/07/12

Signature

Quality Control  
(D. Vitagliano)

*Dario Vitagliano*

The results reported were obtained at the time of release.

## ATTESTATO DI TRATTAMENTO

### Treatment Declaration

**N° 220.764**  
No

**Data 08/07/2019**  
Dated

**N° Rif. Lotto di Trattamento 5270/2019**  
Rif Batch No.

**W.O. 2469530**

**S.O. 2270084**

**Mandante LIOFILCHEM S.R.L. (6)**  
Sender

**Documento di trasporto N.° 9676**  
Delivery note No.

**Del 02/07/2019**  
Dated

**N° colli 5**  
No of Batches

**Ricevente LIOFILCHEM S.R.L. (6)**  
Consignee

**Contratto Commerciale N° 2346/2015**  
Contract No.

**Cliente LIOFILCHEM S.R.L. (6)**  
Customer

**Codice Packing-List www\_6\_66418**  
Packing-List code

#### Descrizione Prodotto (Come indicato nel form della Packing-List elettronica inviata dal Cliente)

Description of goods (As declared in the digital Packing-List sent by the Customer)

060719022-060719023-060619073

Si dichiara che la merce sopra descritta è stata sottoposta a trattamento mediante esposizione a raggi gamma generati da Cobalto-60 utilizzando impianti e procedure di controllo conformi alle norme UNI EN ISO 9001, UNI CEI EN ISO 13485, UNI EN ISO 11137 e GMP.

We hereby declare that the above-mentioned goods have been irradiated with Cobalt-60 gamma rays using machinery and control procedures validated in accordance with UNI EN ISO 9001, UNI CEI EN ISO 13485, UNI EN ISO 11137 e GMP.

Sterigenics Italy si esime dalla responsabilità di eventuali errori di quanto indicato dal Cliente nella Packing-List elettronica  
Sterigenics Italy will not be held responsible for any mistake in what indicated by the Customer in the digital Packing-List

**Il processo di trattamento è stato effettuato secondo le specifiche del Capitolato di Fornitura: N°: 681/14**  
Treatment process has made in compliance with the specifications of the Supply Agreement: No.

**del 29/07/14**  
dated

**Ciclo standard: 12,5 kGy**  
Standard Cycle

**Dose Minima: 15,0 kGy**  
**Dose Massima: 22,3 kGy**

**Dosimetro tipo Red Perspex 4034 Lotto:PN**  
Dosimeter Batch

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Soggetta a Direzione e Coordinamento di Deross Holding B.V.