

Product	Batch	Manufacturing date	Expiration date
<b>BioCapt Tryptic Soy Agar + Neutralizers</b> Ref. 19102S (79001209)	032318029	2018/03/23	2019/03/23

Gamma Rays Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. 208.458	12,5	2018/05/09

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%	80%	Conforms
<i>Escherichia coli</i> ATCC® 8739	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	120%	Conforms
<i>Staphylococcus aureus</i> ATCC® 6538	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	170%	Conforms
<i>Pseudomonas aeruginosa</i> ATCC® 9027	Aerobic, 24-72 h 32.5 ± 2.5°C	70% ≤ P <sub>R</sub> % ≤ 200%	185%	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%	82%	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	2018/05/16	Signature	Quality Control (D. Vitagliano)
The results reported were obtained at the time of release.			<i>Dario Vitagliano</i>

## ATTESTATO DI TRATTAMENTO *Treatment Declaration*

**N°** 208.458  
*No*

**Data** 09/05/2018  
*Dated*

**N° Rif. Lotto di Trattamento** 3611/2018  
*Rif Batch No.*

**W.O.** 2199729  
**S.O.** 1950563

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

**Documento di trasporto N.°** 5817  
*Delivery note No.*

**Del** 18/04/2018  
*Dated*

**N° colli** 2  
*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\_59360  
*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)*

032318029-032218179

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 **del** 29/07/14  
*Treatment process has made in compliance with the specifications of the Supply Agreement: No. dated*

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

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

Sterigenics Italy S.p.A - Via Marzabotto, 4 - 40061 MINERBIO (Bologna - Italia) Tel.  
+39 051 66 05 998 - Fax +39 051 66 05 574 - www.sterigenics.com

Soc. Uninomiale - Capitale Sociale € 2.500.000,00 i.v. - P.Iva IT00500911201  
C.F. e Reg. Imprese di Bologna 00307110379 - R.E.A. Bologna 194057  
Soggetta a Direzione e Coordinamento di Deross Holding B.V.

