Your Partner in Laboratory

ALMECO 500-S Media Bottle

500 ml - Sterile - SAL 10^{-6}

MSE
Rue du Vieux Bourg
49340 Nuaillé
FRANCE

+33 (0) 24164 7341

info@mse-sas.fr

DESCRIPTION

Almeco Square Media bottles are suitable for the storage of media, buffers, serum and cell culture and general use. The square bottle is designed to save space and made of crystal clear PET to obtain the best view of the contents.

TECHNICAL DATA

Item no.	Volume	Weight (g) Single unit (+/- 1.5g) Without cap	Unit per (pcs) Sleeve/Case	Weight (g) Sleeve/Case	Box (mm) Dimension HxWxD
AL-500PET	500 ml	86	25 50	2,420 5,410	400 x 400 x400

Dimensions

Height: 173,5 mm
With screwcap:
177,3 mm
Width: 77,0 mm

Packing - sleeve

Packing - box

	Screwcap Polyethylene	Bottle Polyethylene Teephthalate
Letter symbol	HDPE (High Density)	PET
Graduation	-	ML
Flammability	Combustible	Combustible
Density	0,93 g/cm³	1,38 g/cm³
Hygroscopicity	0,93 g/cm³	<0,1%
Optical properties	Translucent shiny surface	Translucent shiny surface

TECHNICAL APPENDIX

Production
The bottles are manufactured in a clean room environment.

Free from pyrogens and detectable endotoxins
Endotoxins belong to the pyrogens, substances that are eliciting fever. They can influence growth and functionality of tissue cultures. The products are tested systematically with the LAL test to prove the absence of endotoxin. The value of endotoxin is <0,06 EU/ml with few exceptions. Exact data are available from the quality certificates that can be generated under MSE SAS.

Free from detectable RNA/DNA
RNA/DNA are genetic information carriers. Material that is contaminated with RNA/DNA can lead to false positive signals during PCR. They unintentionally amplify along with the desired template. Independent research laboratories periodically test and confirm that no foreign RNA/DNA is detectable with Almeco products.

Free from detectable RNase/DNase
RNases/DNases are enzymes that degrade RNA/DNA. They are components of each living cell and cannot be destroyed by the sterilization process. Independent research laboratories periodically test and confirm that no foreign RNase/DNase are detectable with MSE products.

Free from cytotoxic substances
Cytotoxic substances are cell poisons that have the ability to weaken or even kill cells. All MSE products are free from cytotoxic substances. MSE tests this regularly conforming DIN EN ISO 10993-5.

Leaching
Leaching signifies the slow compounds dissolving (leaching) from plastic ware into buffer and solvents. MSE avoids this by using ultrapure raw-material that is certified to be free of chemical softeners and additive. Recycled raw-material never is processed with MSE products. All raw-material conforms to the medical directives (93/42) and the Pharmacopoeia USP Class VI. In addition during the production optimized molds that work without any slip agents.

Sterility/SAL
Sterility describes the aseptic condition, i.e. the absence of living organism. During the sterilization process transferable organism such as fungus, bacteria or viruses are killed. MSE receives product sterility through a sterile production processes followed by the E-beam sterilization MSE guarantees a "Sterility Assurance Level" (SAL) by standard products 10^{-6}.

REFERENCES
DS/EN ISO 11737-1: 2006/AC 2009 "Sterilization of the medical devices – Microbiological methods – Part 1: Determination of the population of microorganisms on products".
EN ISO 11137-2:2013 "Sterilization of health care products-Radiation – Part 2: Establishing the sterilization dose section 4.3.
European Pharmacopoeia 7.8:2013: Chapter 2.6.1 sterility.
US Pharmacopoeia 36, 2013: Chapter 71, Sterility tests.
ISO 11737-2:2009, "Sterilization of medical devices – Microbiological Methods – Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process, Annex A, Section A6.6.

DATASHEET

BOTTLE

European Regulatory Information Sheet

(Revision date 08.05.2013)

The PET resin used :

- complies with the requirements of the European Legislation (EU) No 10/2011 and all its amendments for plastics used in contact with food.
- is produced under good manufacturing practices in compliance with EU Regulation 2023/2006 and is intended for use to manufacture articles in compliance with the general requirements (in Article 3) of Regulation (EC) 1935/2004.
- are complying with the REACH regulation and SVHC list (the absence of these substances) are BPA free.

Aflatoxins (EU Regulation 466/2001/EC) (EU Regulation 683/2004/EC)	Not present
Alkylphenols	Not present
Amines	Not present
Biocides (EU Directive 98/8/EC)	Not present
CMRs (EU Regulation 1272/2008)	Not present
Colourants (Resolution AP 89(1)) (German BfR) (Recommendation IX)	Not present
Cosmetic Regulation Fragrances (EU Regulation 1223/2009)	Not present
Bis (2-ethylhexyl) Phthalate, DEHP, DOP	Not present
Dimethylformamide (DMF) and Dimethylfumarate	Not present
Emusifiers (EU Directive 2003/53/EC)	Not present
Epoxides (EU Directive 2005/1895/EC)	Complies
Fatty Acids	Not present
Flavourings (EU Dfirective 88/388/EC)	Not present
GMO (EU Directive 2001/18/EC) (EU Regulation 1829/2003) (EU Regulation 1830/2003)	Complies
Heavy Metals (EU Directive 76/769/EEC) (EU Directive 88/378/EEC) (EU Directive 94/62/EC) (EU Directive 2000/53/EC) (EU Directive 2000/76/EC) (CEN EN 71, Part 3) (US CSG (CONEG))	Complies for following: Arsenic (As), Barium (Ba) Cadmium (Cd), Copper (Cu) Hexavalent chromium (Cr (6+)) Lead (pb), Mercury (Hg)
GMP (EU Regulation 2023/2006/EC)	Complies
Heavy Metals – RoHS (EU Directive 2011/65/EU)	Not present
Parabens	Not present
PVC, PVDC , Chlorinated Plastics	Not present
Substances of Animal Origin (EU Regulation 999/2001 and Amendments)	Not present
Triclosan 2,4,4'-trichloro-2'hydroxydiphenyl ether 2010/16/EU	Not present

SCREWCAP

European Regulatory Information Sheet

(Revision date 04.11.2014)

HDPE resin used:

• is produced under good manufacturing practices in compliance with EU Regulation 2023/2006 for materials and articles intended to come into contact with food.
• are complying with the REACH regulation 1907/2006/EC and SVHC list (the absence of these substances).

CMRs (EU Regulation 1272/2008)	Complies
Cosmetic Regulation Fragrances (EU Regulation 1223/2009)	Not present
GMP (EU Regulation 2023/2006/EC)	Complies
Ozone layer (EU Directive 1005/2009/EC)	Complies
Heavy Metals (EU Directive 76/769/EEC) (EU Directive 88/378/EEC) (EU Directive 94/62/EC) (EU Directive 2000/53/EC) (EU Directive 2000/76/EC) (CEN EN 71, Part 3) (US CSG (CONEG))	Complies for following: Arsenic (As), Barium (Ba), Cadmium (Cd), Copper (Cu) Hexavalent chromium (Cr (6+)) Lead (pb), Mercury (Hg)
GMP (EU Regulation 2023/2006/EC)	Complies
Heavy Metals – RoHS (EU Directive 2011/65/EU)	Not present
Organic Pollutants (POPs) (EU Directive 850/2004/EC)	Complies
Allergenes (EU Directive 2003/89/EC) (EC Directive 2006/142/EC) (EU Directive 2007/68/EC) (EU Directive 200/13/EC)	Complies