Product Information Statement

The information contained in this document pertains to the material used to manufacture AltemisLab AlteTube™ products.

REASON FOR USE

To help customers determine if AlteTube™ products are suitable for their application. While we have conducted the tests below, we strongly recommend customers perform their own testing. Samples are available upon request.

Grade of Material;
Virgin Grade Polyproplene. SJ-170M; is a homo polymer resin produced through the polymerization of propylene. This grade is designed to be processed in conventional Injection moulding equipment and shows good thermal stability and high melt-flow.

Features:

- **Thermal Stability**– can withstand high temperatures without degradation..
- **High Transparency** – allows for clear visibility.
- **High Melt-Flow** – for easy processing during injection moulding.

CE Certification vs. CE Marking – What This Means for AltemisLab Products

At AltemisLab, we often receive questions about CE marking and our product compliance. It's important to understand that while our products are CE certified, they are not CE marked—and for good reason.

According to the European Commission's 2012 guidelines, CE marking is required only for in vitro diagnostic medical devices that are specifically intended for defined diagnostic procedures. Further clarification published in 2021 by leading European life science organisations (GAMBICA, FHI, LABMAS, Laborama, SPECTARIS) confirms that general laboratory products—such as sample storage tubes—should not carry CE marking.

CE marking is a visible symbol that a product complies with relevant EU directives related to safety, health, and environmental protection. While essential for certain product categories (e.g. medical devices, electronics, toys), it is not applicable to general laboratory consumables.

AltemisLab's products are manufactured under ISO 9001 and ISO 14001 certified conditions, ensuring high standards of quality and environmental management. We hold the necessary CE certification documents to support the compliance of our materials, but as our sample storage tubes are classified as general laboratory prodcuts and not medical devices or diagnostic tools, CE marking cannot be applied.

AltemisLab certifies that this product meets the following criteria, in reference to the medical grade virgin polypropylene:

Product Information	
Chemical Name	Polypropylene
Other Names	Resin
Grade	SJ-170M
CAS no.	9003-07-0
Content (wt%)	>=95 ~<=100
Features	• For Medical Injection Moulding • High rigify, high transparency • USP Class VI FDA DMF, Gamma Ray and E-beam Sterilization Stability

	Test Method/Standard	**Unit**	**Value**
Physical Properties			
Melt Flow Index, MFI (230^{O}C, 2.16kg)	ASTM D 1238	g/10min	26.0
Density	ASTM D 792	g/cm^3	0.9
Mechanical Properties			
Tensile Strength at Yield	ASTM D638	Kfg/cm^3	370
Elongation at break	ASTM D638	%	≥100
IZOD Impact Strength	ASTM D256	Kgf.cm/cm	3.0
Load Deflection Temperature ((4.6kg/f/cm^3))	ASTM D648	^{O}C	115

Endotoxin (Pyrogens):

AlteTubes have been tested according to ISO 10993-5:2009, USP, Biological Reactivity Test, In Vitro with Limulus Amebocyte Lysate (LAL) reagent. No pyrogens were detected.
Results: Test sample extraction had an undetectable level of endotoxin at <0.25 Eu/mL.

Leachables and Extractables Testing

During the manufacturing of plastic consumables, certain chemical compounds are often used to enhance product stability, durability, and performance. However, these compounds—known as leachables and extractables—can pose a risk to scientific integrity by introducing variables that may interfere with sensitive assay systems.

Extractables are compounds that can be drawn out of the material when exposed to solvents under laboratory conditions.
Leachables are compounds that migrate into the sample during normal use, due to direct contact with the container.

To ensure the highest standards of sample integrity and experimental reliability, our AlteTube™ 2D tubes have been rigorously tested for both extractables and leachables. Testing confirms that these compounds are not present in our tubes, helping reduce the risk of assay interference and contamination.

AlteTubes, including all components used in the packaging, are free of;
lead (Pb), cadmium (Cd), mercury (Hg), and hexavalent chromium (Cr6+).

This product does not contain phthalates.
This product does not contain latex.
This product does not contain Bisphenol A (BPA).

Protocol used an extract profile for the above tests, carried out by STERIS.
(STERIS Applied Technologies is a global provider of contract sterilization, laboratory testing and product and packaging testing services; and integrated sterilization equipment, control systems, and radiation dosimetry to support medical device and pharmaceutical manufacturers.
Address: NETPark: Plexus 2,
Thomas Right Way,
Sedgefield.
County Durham. UK.
TS21 3FD.)

PCR Inhibitors

qPCR and rt-qPCR testing confirms AlteTubes are free from DNA, DNase, RNA and RNase.

Batch Consistency

Customers may request product manufactured from a single batch or Lot No.

Barcode Reading Test:

Each tube is permanently laser-etched with 2D barcodes that are unique for each tube.
Every coded tube is checked for 100% readability and uniqueness.

Leak Testing:

Tubes are periodically tested for leaks.

AlteClean™ Sterile

AlteClean™ Sterile products meet the AlteClean™ specifications for non-viable contaminants and have also been Electron Beam (E-beam) treated, meeting a minimum requirement of 10^{-6} SAL (Sterility Assurance Level).

E-Beam Sterilisation is a form of ionizing energy that is characterized by its low penetration and high-dosage rates. The beam, a concentrated, highly charged stream of electrons, is generated by accelerators capable of producing continuous or pulsed beams. As the product/material being sterilized passes the E-Beam, energy from the electrons is absorbed, altering various chemical bonds, damaging the DNA, and destroying the reproductive capabilities of the micro-organisms.

Test:
Validation of E-Beam sterilisation to ensure the sterility assurance level (SAL) 10^{-6}

Conclusion
When the sterilisation dose (21.94kGy) used to irradiate under routine process, the minimum sterilisation dose of 15kGy is achieved and the maximum dose is managed under acceptable dose (45kGy) in the product, so process effectiveness of E-Beam sterilisation is established, and the aseptic guaranteed level (SAL) is 10^{-6}.

Amber colour concentrates

Product Information:

Chemical Name: Brown Polypropylene Based Colour Concentrates

CAS No.: 13463-67-7

Item	Unit	Value
Heat Stability	Degrees Celsius	280
Heavy Metal Free	N/A	YES
Diarylide Free	N/A	YES
Light Fastness	Grade (Blue Wool)	8

Storage: Store at cool and dry place and protected from sunlight.

Transport by aircraft:

AlteClean™ meet the pressure requirements for transportation by aircraft as per the 63rd edition of IATA Dangerous Goods Regulations (The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa.)

95kPa pressure differential tests were performed and upon testing at the various temperature ranges, no leaks were detected after each test. The following table provides a summary of the test.

Test	Observation	Results
Dwell at +55OC for 30 mins followed by 1hr 95kPA pressure differential	No leaks detected	Pass
Dwell at -40OC for 30 mins followed by 1hr 95kPA pressure differential	No leaks detected	Pass

Treatment: Vortexing and Centrifugation

Centrifugation, max. RCF
5800 x g: swinging-bucket rotor
26000 x g: fixed angle rotor

PLEASE NOTE: for full or partially racked tubes, tubes must be supported from underneath to prevent damange to the rack.
Centrifugation to be done at ambient temperatures.

Septum caps mats and use with DMSO

Component material: TPE (thermoplasticelastomer)
AlteTube Septum cap mats are made of an advanced thermoplastic elastomer (TPE). They are suitable for use with DMSO-based samples due to the high chemical resistance of TPE. Properties of TPE also include low evaporation and water uptake in DMSO based samples*

*we recommend you carry out your own testing in case of a more specific application.

Emma Ryan
Director

AltemisLab Ltd
Vanilla House, Copley Hill Business Park,
Babraham, Cambridge, CB22 3GN
United Kingdom
+44 (0) 1223 344900
Company Number: 11188771

Declaration of Conformity

AltemisLab certifies that our AlteTube™ manufacturer site meets the below standards under the EU Directive 2011/65/EU of the European Parliment and of the Council of the 8th June 2011.

CE

Declaration of Conformity

Product Name : AlteTube SBS Tubes

Reference Report No. : ATL-RoHS-250226-1

The above product has successfully demonstrated that its product is in compliance with

Restriction Environmental of Hazardous Substances Directive

This declaration of conformity is issued under the sole responsibility of the manufacturer. The Object of the declaration does not contain any of the substances in excess of the maximum concentration values in EU Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, unless the substances are in an application that is exempt under RoHS.

Maple LS corporation. is compliant with the amendment to ANNEX 2, dated March 31, 2015 additionally restricts the use of DEHP, BBP, BDP and DIBP in Electrical and Electronic Equipment and becomes effective July 22, 2019.

The following technical specifications have been applied :

IEC 62321-4:2013+AMD1:2017 CSV, IEC 62321-5:2013,
IEC 62321-6:2015, IEC 62321-7-1:2015,
IEC 62321-7-2:2017, IEC 62321-8:2017

We, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s)

Date of Issue : Mar. 20, 2025

Manufacturer Signature :

ISO 9001:2015 Certification

AltemisLab certifies that our AlteTube™ manufacturer site Environmental Management System has been assessed by Orion Registrar and found to be in compliance with the above quality standard.

Orion Registrar, Inc.
Thorough and Fair Auditing

Certificate of Certification

Has been assessed by Orion Registrar and found to be in compliance with the following Quality Standard:

ISO 9001:2015

The Quality Management System is applicable to:

Manufacture and Service of Physical and Chemical Equipment

The Certification period is from

March 21, 2024 to May 3, 2027

This certification is subject to the company maintaining its system to the required standard and applicable exceptions, which will be monitored by Orion.

Certification Identification: KOR-3127-18-03

ANAB ACCREDITED

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

4/1/2024
Paul M. Burck, President *Date*

7502 W. 80th Avenue, Suite 225 ▾ Arvada, Colorado 80003 ▾ 303-456-6010 ▾ FAX 303-456-6681 ▾ www.orion4value.com
To authenticate this certificate, please visit: http://www.orion4value.com/about-orion/registered-companies/

ISO 14001:2015 Certification

AltemisLab certifies that our AlteTube™ manufacturer site Environmental Management System has been assessed by Orion Registrar and found to be in compliance with the above quality standard.

Orion Registrar, Inc.
Thorough and Fair Auditing

Certificate of Certification

Has been assessed by Orion Registrar and found to be in compliance with the following Environmental Management Standard:

ISO 14001:2015

The Environmental Management System is applicable to:

Manufacture and Service of Physical and Chemical Equipment

The Certification period is from

March 21, 2024 to May 3, 2027

This certification is subject to the company maintaining its system to the required standard and applicable exceptions, which will be monitored by Orion.

Certification Identification: KOR-EMS-3127-18-03

ANAB ACCREDITED

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

Paul M. Burck, President — 4/1/2024 Date

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