Material : S71
6-Layer High Gas Barrier Film

Film characteristics

- EVAM® fluid contact layer
- Conformance with ISO and USP Biocompatibility Standards
- Excellent clarity
- Sterilization by Gamma

Main applications

- Drug delivery
- Parenteral nutrition
- Ideal for O2 sensitive drugs

Range of bag sizes

- 50mL – 5L

Description

- S71 is a multi layer co-extruded high gas-barrier film containing ethylene vinyl acetate copolymer (EVAM®) as a fluid contact layer and ethylene vinyl alcohol copolymer (EVOH) as gas and water vapor barrier layer (EVA / EVOH / EVA / EVAM®).
- The film is manufactured by blown extrusion in our class ISO 7 cleanroom.

Film Mechanical Typical Values

The following properties are typical values obtained on freshly irradiated film with a minimum dose of 25 kGy.

- Tensile Strength (N / mm^2):

Machine Direction:	210
Transverse Direction:	180

- Elongation @ Break (%):

Machine Direction:	440
Transverse Direction:	540

Operating temperatures
The mechanical properties of the S71 film have been validated between -70°C and 45°C. The use of S71 bags at temperatures

Sartorius Croatia - Libra elektronik d.o.o.
Savska 45A, 10 290 Zaprešić
Ovlašteno zastupstvo i servis Sartorius RH
Sartorius.Croatia@email.t-com.hr, service@sartorius.hr
www.Sartorius.hr
Tel: 01 3340-290/291/293/295/296, fax: 01 3340-299
P.J. Solin, Zgon 80, 21210 Solin, 091 563 2266

outside this range cannot be guaranteed. Additional application development trials and/or validation in accordance with the actual process conditions must be performed with the support of Sartorius Stedim Biotech Application Engineering Group.

Permeability to gases and water vapor

- O_2 Transmission Rate @ 23ºC – RH Ext side : 50%
  - RH internal side : 90% (ASTM D3985)

(cc / m^2 per 24 hours / 1 atm) 300 µm Film	15.7
(cc / m^2 / per 24 hours / 1 atm) 360 µm Film	7.8

- H_2O_{vap} Transmission Rate @38ºC – 90% RH (ASTM F1249)

(g / m^2 per 24 hours) 300 µm Film	7.4
(g / m^2 per 24 hours) 360 µm Film	5.0

Method of Welding

- Radio Frequency

Method of Sterilization

- Gamma Irradiation

Regulatory Information

- Drug Master File No. 13014 on bags manufactured with S71 is available for registration dossiers.
- Registered device manufacturer with the FDA - Class II medical devices.
- The Evam® contact layer meets the requirements of the European Pharmacopoeia 1998 chapter 3.1.7 [Ethylene-vinyl-acetate copolymer for containers and tubing for total parenteral nutrition preparations].

Environmental Impact

- S71 film disposal may be done in an approved landfill or preferably by incineration under locally approved conditions.
- At temperatures above 238ºC, S71 film will release decomposition products, which may include acetaldehyde, crotonaldehyde, acetone, acetic acid, carbon monoxide and dioxide, hydrocarbons.

Bio-compatibility Testing

- The following tests have been performed on freshly irradiated film with a minimum dose of 25 kGy according to USP <88> (Plastic Class VI) Test and ISO 10993 studies:

Cytotoxicity Study using ISO Elution method	ISO 10993-5	USP<87>
Actute Intracutaneous Reactivity Study in the rabbit	ISO 10993-10	USP<88>

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Acute Systemic Toxicity in the mouse	ISO 10993-11	USP<88>
Muscle Implantation Study in the rabbit	ISO 10993-6	USP<88>
Sensitization Study in the guinea pig	ISO 10993-10	
Subchronic Intravenous Toxicity Study in the rat	ISO 10993-11	
Genotoxicity: Reverse Mutation Study	ISO 10993-3	
Haemocompatibility Studies	ISO 10993-4	

(Clotting Time Coagulation, Hemolysis, $C3_a$)

- The following tests have been performed on 2 years artificially aged irradiated film according to USP <88> (Plastic Class VI) Test and ISO 10993 studies:

Acute Intracutaneous Reactivity Study in the rabbit	ISO 10993-10	USP<88>
Acute Systemic Toxicity in the mouse	ISO 10993-11	USP<88>
Muscle Implantation Study in the rabbit	ISO 10993-6	USP<88>

- Film irradiated was tested and passed the USP<661> Physico-chemical tests for plastics.