

Material : EVAM®

Ethylene Vinyl Acetate Co-Polymer

Film characteristics

- Conformance with ISO and USP Biocompatibility Standards
- Mono or Multi-chamber bags
- No plasticizers
- Excellent clarity
- Sterilization by ETO or Gamma

Main applications

- Drug delivery
- Parenteral nutrition

Range of bag sizes

- 50mL – 5L

Description

- EVAM® is a monolayer film made of high purity ethylene vinyl acetate 18%.
- 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 / mm²):

Machine Direction: 150

Transverse Direction: 110

- Elongation @ Break (%):

Machine Direction: 500

Transverse Direction: 670

- Temperature Range: -85°C to +45°C

Permeability to gases and water vapor

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- O₂ Transmission Rate @ 23°C – 65% RH (ASTM D3985)

(cc / m² per 24 hours / 1 atm) 1 080

(cc / 100 inch² per 24 hours / 1 atm) 69.7

- CO₂ Transmission Rate @ 23°C – 65% RH (ASTM D3985)

(cc / m² per 24 hours / 1 atm) 10 320

(cc / 100 inch² per 24 hours / 1 atm) 665

- H₂O_{vap} Transmission Rate @ 37°C – 90% RH (NF H00-044)

(g / m² per 24 hours) 2.9

(g / 100 inch² per 24 hours) 0.187

Method of Welding

- Radio Frequency

Method of Sterilization

- Ethylene oxide (ETO) sterilization
- Gamma Irradiation

Regulatory Information

- Drug Master File No. 12633 on bags manufactured with EVAM[®] is available for registration dossiers.
- Registered device manufacturer with the FDA - Class II medical devices.
- The EVAM[®] film 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

- EVAM[®] film disposal may be done in an approved landfill or preferably by incineration under locally approved conditions.
- At temperatures above 238°C, EVAM 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>
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>
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	
Mutagenicity	ISO 10993-3	
Haemocompatibility Studies	ISO 10993-4	

(Clotting Time, Hemolysis)

- 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:

Cytotoxicity Study using ISO Evolution method	ISO 10993-5	USP<87>
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>
Hemolys slides	ISO 10993-4	USP<88>

- Film freshly irradiated at 50 kGy was tested and passed the USP<661> Physico-chemical tests for plastics.