MATERIAL SAFETY DATA SHEET
Leepol™ Coat L-30DA

THE LEELA CORPORATION

Leepol™ Coat L-30DA

Add the following:

★ **Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion**
(Title for this monograph – to become official DEC 29, 2021)
(Prior to DEC-29- 2021, the current practice of labeling the article of commerce with the name Methacrylic Acid Copolymer Dispersion may be continued. Use of the name Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion will be permitted as of DEC-30-2016, but the use of this name will not be mandatory until DEC-29-2021. The 60-month extension will provide the time needed by manufacturers and users to make necessary changes.)

DEFINITION

Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion is an aqueous dispersion of Methacrylic Acid and Ethyl Acrylate Copolymer. It contains, on the basis of the calculated amount of dry substance in the Dispersion, NLT 46.0% and NMT 50.6% methacrylic acid units. Itmay contain suitable surface-active agents.

IDENTIFICATION

- **A. INFRARED ABSORPTION <197K>** : Proceed as directed , except to use the residue obtainedin the test for Loss on Drying as the sample.
- **B.** It meets the requirements of the Assay.

ASSAY

- **PROCEDURE**

  Sample : 2.5 g of the Dispersion

  Titrimetric System

  (See Titrimetry <541>)

  Mode: Direct titration

Titrant: 0.1 N sodium hydroxide VS

Endpoint detection: Potentiometric

Analysis: Dissolve the sample in 100 ml of neutralized acetone. Titrate the solution as directed in Titrimetric system. Each ml of 0.1 N sodium hydroxide is equivalent to 8.609mg of methacrylic acid units.

Calculate, on the dried basis, the percentage of methacylic acid units in the portion of Dispersion taken :

$$\text{Result} = [V \times N/W \times (100 - L)] \times 860.9$$

V = Volume of titrant consumed (ml)

N = normality of the titrant

W = weight of Dispersion taken (g)

L = percentage of the Loss on Drying value for the Dispersion

Acceptance criteria : 46.0% - 50.6% based on the calculated amount of dry substance in the Dispersion.

IMPURITIES

Inorganic Impurities

- **RESIDUE ON IGNITION <281> :** Using mild heating conditions (e.g. , steam bath, sand bath) to avoid loss of material, evaporate the Dispersion to dryness prior to ignition: NMT 0.2% residue is obtained, calculated on the undried Dispersion basis.
- **HEAVY METALS, Method II <231> :** Using mild heating conditions (e.g. , steam bath, sand bath) to avoid loss of material, evaporate the Dispersion to dryness prior to wetting with sulfuric acid and ignition : the color of the solution from the test preparation is not darkerthan that of the solution from the standard preparation (20 ppm).

Organic Impurities

- **LIMIT OF MONOMERS**

  Sodium perchlorate solution : Dissolve 3.5 g of sodium perchlorate in 100 ml of water. This solution has a concentration of 0.25 M.

  Mobile phase : Add phosphoric acid dropwise to water to obtain a solution having a pH of 2.0 Prepare a mixture of this acidified water and methanol (80:20), and degas.

  Standard solution : Dissolve 0.01 g of methacrylic acid and 0.01 g of ethyl acrylate in 5 ml of butanol, and add methanol to make exactly 100 ml. Transfer 1.0 ml of this solution to a 100 ml volumetric flask, and dilute with methanol to volume. Mix 5.0 ml of this solution with 5.0 ml of sodium perchlorate solution, accurately measured. This solution contains about 0.5 µg/ml each of methacrylic acid ethyl acrylate.

Sample solution : Transfer a quantity of Dispersion, equivalent to 3 g of solids on the driedbasis, to a 50-ml volumetric flask, dilute with methanol to volume, and mix. Add 5 ml of this solution dropwise while continuously stirring into a beaker that contains 5 ml of sodium perchlorate solution, accurately measured. Remove the precipitated polymer by centrifugation (e.g., NLT 5000 × g for NLT 5 min). Use the clear supernatant.

Chromatographic system

(See Chromatography <621> , System Suitability.)
Mode: LC
Detector: UV 202 nm
Column: 4.0-mm × 12.5-cm; 7-µm packing L1
Flow rate: 2 ml/min
Injection size: 20 µl

System suitability

Sample: Standard solution

[NOTE – The relative retention times for methacrylic acid ethyl acrylate are 1.0 and 2.6,respectively.]

Suitability requirements

Resolution: NLT 2.0 between methacrylic acid and ethyl acrylate

Relative standard deviation: NMT 5.0%, determined for each analyte

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of each monomer in the solid portion of the Dispersion taken:

$$\text{Result} = (r_U \mid r_S) \times (C/W) \times V_F \times D \times F \times 100$$

r_U = monomer (methacrylic acid or ethyl acrylate) peak response from the sample solution

r_S = monomer (methacrylic acid or ethyl acrylate) peak response from the Standard solution

C= concentration of the monomer (methacrylic acid or ethyl acrylate) in the Standard solution (µg/ml)

W = solid weight of the Dispersion, calculated on the dried basis, taken to prepare the Sample solution (g)

V_F = final volume of the Sample solution, 10 ml

D = dilution factor for preparation of the sample solution, 10

F = conversion factor, 10^{-6} g/µg

Acceptance criteria: NMT 0.01% of total monomers, based on the weight of the solid portion of the Dispersion taken

SPECIFIC TESTS

- **COAGULUM CONTENT:** Weight a Stainless Steel sieve having 90-µm openings or a suitablesingle-woven wire cloth with a mesh width of 90 µm, and filter 100 g of the Dispersion through it. [NOTE – Suitable single-woven wire cloth mesh meets the requirements set in ISO 9044.] Wash the sieve or the cloth with distilled water until a clear filtrate is obtained,and dry the sieve or the cloth to constant weight at 110° : the weight of the residue does not exceed 1000 mg (1%).
- **LOSS ON DRYING <731> :** Dry a sample at 110° for 6 h : it loses 68.5% - 71.5% of its weight.
- **MICROBIOL ENUMERATION TESTS <61> and TESTS FOR SPECIFIED MICROORGANISMS <62> :** The total aerobic microbial count does not exceed 10^3 cfu/g, and the total combined molds and yeasts count does not exceed 10^2 cfu/g.

pH <791> : 2.0-3.0

ROTATIONAL RHEOMETER METHODS <912> : Equip a suitable rotational viscometer with an adapter comprising a cylindrical spindle rotating within an accurately machined chamber (or tube). 1) Mix the Dispersion, pipet the volume of test specimen recommended by the instrument manufacturer into the chamber (or tube), and ensure that the temperature of the test specimen is at 20 ± 0.1° . The shear rate under the test condition is NLT 1 s^{-1} and NMT 100 s^{-1} .2) Measure the apparent viscosity following theinstrument manufacturer's directions.

Acceptance criteria: The viscosity is between 2 and 15 mPa.s.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers. Store at controlled roomtemperature. Protect from freezing.
- **LANELING:** The label indicates the name and amount of any substance added as asurface-active agent.
- **USP REFERENCE STANDARDS** <11>
  USP Methacrylic Acid and Ethyl Acrylate Copolymer (1:1) RS (USP Methacrylic Acid Copolymer, Type C RS)

★ NF30

1. A commercial device is available from Brookfield as an ultra-low (UL) viscosity adapter. The adapter comprises a 0.4-cm diameter shaft, an accurately machined chamber (or tube) with an internal diameter of 2.8 cm and a depth of 13.5 cm, and a cylindrical spindle 2.5 cm in diameter and 9.1 cm in height.
2. The cylindrical spindle rotates at 30 rpm.

Auxiliary Information – Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
Monograph	Robert H. Lafaver, M.S. Scientific Liaison 1-301-816-8335	(EXC2010) Monographs-Excipients
<61>	Radhakrishna S Tirumalai, Ph.D. Principal Scientific Liaison 1-301-816-8339	(GCM2010) General Chapters-Microbiology
<62>	Radhakrishna S Tirumalai, Ph.D. Principal Scientific Liaison 1-301-816-8339	(GCM2010) General Chapters-Microbiology
Reference Standards	RS Technical Services 1-301-816-8129 rstech@usp.org	

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