

## **Product Specification**

## CARBOPOL®\* 940 NF POLYMER

Carbopol® 940 NF polymer meets the limits cited in the current edition of the following monograph:

United States Pharmacopeia/National Formulary (USP/NF) monograph for Carbomer 940

## **General Product Characteristics**

Appearance: White, fluffy powder Odor: Slightly acetic

Test	Specification	Lot Test Frequency <sup>1</sup>	Test Procedure <sup>2</sup>
Identification			
Colorimetric test	Pass	1:200	USP/NF
Gel formation test	Pass	1:200 <sup>3</sup>	USP/NF
Carboxylic Acid Content, Assay %	56.0 - 68.0	1:1	Lubrizol 1318-A
Viscosity, cP, 25°C			
Brookfield RVT, 20 rpm, neutralized to pH 7.3 - 7.8			
0.5 wt% mucilage, spindle #7	40,000 - 60,000	1:1	Lubrizol 430-l
Clarity, % Transmission			
0.5% Dispersion, neutralized, 420 nm	85 min	1:1	Lubrizol 485-D
Loss on Drying, %	2.0 max	1:1	USP/NF
Heavy Metals, ppm			
Total heavy metals, as Pb	20 max	1:200	USP/NF
Specific metals: Hg, Pb, As, Sb	10 max	1:200	Lubrizol SA-012
Residual Solvent <sup>4</sup> , ppm			
Benzene	1,000 max	1:1	Lubrizol SA-095
Residual Monomer, ppm			
Free acrylic acid	2,500 max	1:1	Lubrizol SA-005

Where lot test frequency is less than 1:1, Lubrizol Advanced Materials, Inc. certifies that each batch/lot meets requirements for the characteristics based on historical process and product data. Because these characteristics are tested on a skip-lot test frequency, results are not reported on the Certificate of Analysis.

- <sup>2</sup> Lubrizol test procedures have been cross-validated to specified compendial procedure(s) or validated if they are included in the monograph.
- <sup>3</sup> Gel formation is confirmed by the viscosity test procedure (Lubrizol 430-I) for each lot of polymer that is produced. Every 200 lots, the gel formation test is conducted according to USP requirements.
- 4 No other residual solvents as listed in USP/NF <467> (Class 1, 2, 3, Table 4 or any other solvents) or Ph. Eur. 2.4.24 are used in the manufacturing process of this product. Since the monograph specifies a limit for benzene, the Residual Solvents test <467> limit for benzene is superseded by the monograph limit.

## Lubrizol Advanced Materials, Inc. / 9911 Brecksville Road, Cleveland, Ohio 44141-3247 / TEL: 800.379.5389 or 216.447.5000

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