

CARBOPOL® 1342 NF POLYMER

Carbopol® 1342 NF polymer meets the limits cited in the current edition of the following monograph:

- United States Pharmacopeia/National Formulary (USP/NF) monograph for Carbomer 1342

General Product Characteristics

Appearance: White, fluffy powder

Odor: Slightly acetic

Test	Specification	Lot Test Frequency ¹	Test Procedure ²
Identification			
Colorimetric test	Pass	1:200	USP/NF
Gel formation test	Pass	1:200 ³	USP/NF
Carboxylic Acid Content, Assay %	52.0 - 62.0	1:1	Lubrizol 1318-A
Viscosity, cP, 25°C			
Brookfield RVT, 20 rpm, neutralized to pH 7.3 - 7.8			
1.0 wt% mucilage, spindle #6 ⁴	9,500 - 26,500	1:1	Lubrizol 430-I
1.0 wt% mucilage with 1.0 wt% salt, spindle #5	5,500 - 15,000	1:1	Lubrizol SA-016
Loss on Drying, %	2.0 max	1:1	USP/NF
Residual Solvent⁵, ppm			
Benzene	1,000 max	1:1	Lubrizol SA-095
Residual Monomer, ppm			
Free acrylic acid	2,500 max	1:1	Lubrizol SA-005

¹ 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.

² Lubrizol test procedures have been cross-validated to specified compendial procedure(s) or validated if they are included in the monograph.

³ 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 For measurements below 10,000 cP, use spindle #5.

⁵ 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 limit for benzene is superseded by the monograph limit.

The information contained herein is believed to be reliable, but no representations, guarantees or warranties of any kind are made as to its accuracy, suitability for particular applications or the results to be obtained. The information often is based on laboratory work with small-scale equipment and does not necessarily indicate end product performance or reproducibility. Formulations presented may not have been tested for stability and should be used only as a suggested starting point. Because of the variations in methods, conditions and equipment used commercially in processing these materials, no warranties or guarantees are made as to the suitability of the products for the applications disclosed. Full-scale testing and end product performance are the responsibility of the user. Lubrizol Advanced Materials, Inc. shall not be liable for and the customer assumes all risk and liability for any use or handling of any material beyond Lubrizol Advanced Materials, Inc.'s direct control. The SELLER MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Nothing contained herein is to be considered as permission, recommendation nor as an inducement to practice any patented invention without permission of the patent owner.