CARBOPOL® 981 NF POLYMER

Carbopol® 981 NF polymer meets the limits cited in the current edition of the following monograph:

- Japanese Pharmaceutical Excipients (JPE) Monograph for Carboxyvinyl Polymer†

General Product Characteristics

Appearance: White, fluffy powder
Odor: Odorless or faint characteristic odor
Solubility: Practically insoluble in diethyl ether; Swells in polar solvents

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
<th>Lot Test Frequency</th>
<th>Test Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identification</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gel formation test</td>
<td>Pass</td>
<td>1:200</td>
<td>Lubrizol SA-098</td>
</tr>
<tr>
<td>Calcium chloride precipitate test</td>
<td>Pass</td>
<td>1:200</td>
<td>Lubrizol SA-098</td>
</tr>
<tr>
<td>Magnesium sulphate precipitate test</td>
<td>Pass</td>
<td>1:200</td>
<td>Lubrizol SA-098</td>
</tr>
<tr>
<td>Infrared spectrum</td>
<td>Pass</td>
<td>...</td>
<td>Lubrizol SA-102</td>
</tr>
<tr>
<td><strong>Carboxylic Acid Content Assay, %</strong></td>
<td>58.0 - 63.0</td>
<td>1:1</td>
<td>Lubrizol 1318-A</td>
</tr>
</tbody>
</table>

**Viscosity, cP, 20°C**
Brookfield RVT, 20 rpm, neutralized to pH 7.0 - 7.5

- 0.2 wt% mucilage, spindle #4 (< 10,000 cP) or spindle #6 (≥ 10,000 cP)
  - 1,500 - 50,000
  - 1:1
  - Lubrizol SA-036

**Viscosity, cP, 25°C**
Brookfield RVT, 20 rpm, neutralized to pH 7.3 - 7.8

- 0.2 wt% mucilage, spindle #4
- 0.5 wt% mucilage, spindle #5
  - 1,000 - 6,000
  - 4,000 - 10,000
  - 1:1
  - Lubrizol 430-I
  - Lubrizol 430-I

**Loss on Drying, %**

- 7.0 max
- 1:1
- JPE

**Purity**

- Heavy metals, ppm
  - 10 max
  - 1:200
  - JPE
- Arsenic, ppm
  - 2 max
  - 1:200
  - JPE
- Acrylic acid, ppm
  - 10,000 max
  - 1:1
  - Lubrizol SA-005

**Sulphated Ash, % (Residue on Ignition)**

- 2.5 max
- 1:200
- USP

**pH, 0.2% Dispersion**

- 2.5 - 4.0
- 1:200
- Lubrizol SA-087

---

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 Infrared reference spectra available upon request.

4 For measurements below 2,000 cP, use spindle #3.

Lubrizol tests and certifies select lots of product against the JPE requirements.

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.