LUBRIZOL LIFE SCIENCE

HEALTH

Aqueous Vagina Gel

This aqueous vaginal gel features **Carbopol® 974P NF polymer** which imparts viscosity, acidic and bioadhesive properties to the formulation.

Number	Ingredients	% w/w
	Part A:	
1.	**Carbopol® 974P NF polymer**	2.00
2.	Deionized water	78.80
	Part B:	
3.	Sodium methylparaben	0.18
4.	Sodium propylparaben	0.02
5.	Deionized water	4.00
	Part C:	
6.	Glycerin	15.00
	TOTAL:	**100.00**

Lab batch size - 600 g

Process:

1. **Part A (Carbopol polymer dispersion phase):** Add purified water in a vessel equipped with dispersing type or propeller type impeller. Disperse Carbopol® 974P NF polymer into the water by submerging the impeller until it is very close to the bottom of the vessel. Angle the impeller to generate a vortex that is 1 to 1½ impeller diameters. Slowly sift the polymer through a stainless steel 20 mesh screen into the vortex of the rapidly agitating liquid (about 800-1500 rpm). Increase the agitation as the viscosity of the dispersion increases to maintain a vortex. After all the dry polymer has been introduced, reduce the agitation to 400-600 rpm and reposition the mixer to vertical position to avoid or minimize air entrapment. Continue the agitation for about 45 minutes, or until a uniform dispersion is obtained.

2. **Part B:** Dissolve the sodium parabens in water and add this salt solution to the Part A ingredients.

3. Add glycerin to the Part A + B mixture and mix with a low-shear impeller thoroughly.

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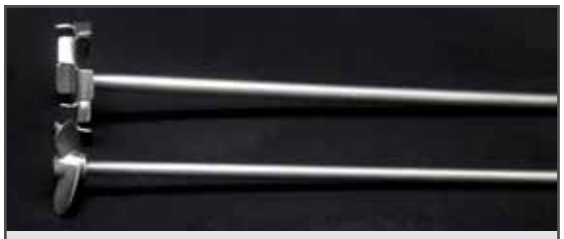
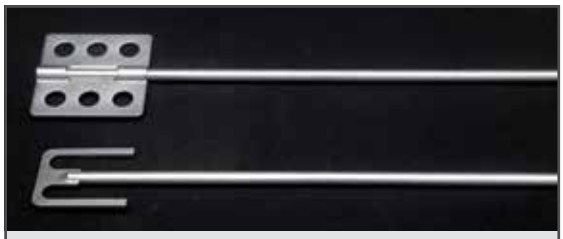
Product Properties	Stability
Appearance: Clear Gel	Passed 3 freeze/thaw cycles
pH: 3.6	Stable for a minimum of 6 months when stored under the following ICH conditions: Long term (25 ± 2°C / 60 ± 5% relative humidity)
Viscosity (cP)* : 45,500 • *Brookfield RVT @25°C, 20 rpm, Spindle #7, measured at 24 hours	Accelerated (40 ± 2°C / 75 ± 5% relative humidity)

Design of mixing elements:



Propeller or dissolver for dispersing Carbopol® polymers.



Paddle or U-shaped low-shear impeller for neutralization.

Summary:

Carbopol® polymers have demonstrated to be useful and highly efficient as rheology modifiers for low-pH aqueous gel.

Alternative Lubrizol products to use in this formulation are Carbopol® 971P NF and Noveon® AA-1 polycarbophil.

The Lubrizol Life Science Health website **www.lubrizol.com/Health** provides additional information:

- Bulletin 04 - Dispersion Techniques; Bulletin 07 - Flow and Suspension Properties; Bulletin 08 - Emulsification Properties; Bulletin 21 - Formulating Semisolid Products
- Dispersion and neutralization videos under video gallery
- Technical Data Sheets, Test Procedures, Certificates, and other Formulations

Please contact your Lubrizol representative to get samples, quotations or further technical assistance.

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