

BFGoodrich

The BFGoodrich Company
Geon Vinyl Division
6100 Oak Tree Boulevard
Cleveland, Ohio 44131
216-447-6000

AN 8373
20674

December 15, 1992

Susan Banovic
Nalge
75 Panaroma Creek
Rochester, NY 14625

SUBJECT: GEON 102EP - FDA STATUS

Dear Ms. Banovic:

Geon 102EP is a homopolymer polyvinyl chloride (PVC) resin. Polyvinyl Chloride is prior sanctioned for use in general food contact applications, both flexible and rigid. The prior sanction is based on an article by A. J. Lehman, from the FDA, published in the Journal of the Association of Food and Drug Officials, July, 1951.

The current Food Manufacturing Practice (GMP) specifications for prior sanctioned PVC are a maximum volatility of 3.0% (1 hour at 105° C) and an inherent viscosity of not less than 0.35 by ASTM D-1243-79. Geon 102EP meets the GMP specifications for prior sanctioned PVC and therefore meets the current FDA requirements for general food contact applications.

PVC is also listed as an acceptable ingredient of food contact articles under 21CFR:

175.105	177.1200
175.300	177.2250
176.180	179.45
177.1010	

I am enclosing a technical data sheet on Geon 102EP. If you have any questions, please contact me at (216) 447-7831.

Sincerely,

THE BFGOODRICH COMPANY

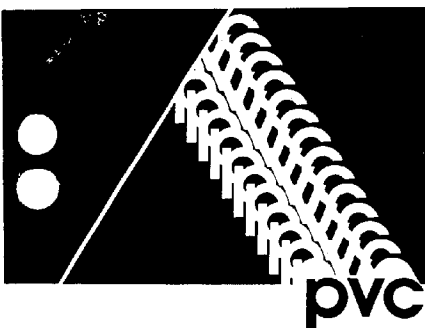
Connie N. Dillon
Connie N. Dillon
Regulatory and Data System Specialist

1215-1/jp

Enclosure

BFG15981

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Geon® 102 EP

SPECIAL PURPOSE RESIN

General Description

Type	Polyvinyl Chloride Homopolymer Resin
Polymerization Process	Suspension
Appearance	White, free flowing powder

Features & Uses

- Flexible compounds
- Electrical wire coating
- High tensile strength flexible products

Typical Properties

ASTM Classification	GP-6-15443
Specific Gravity	1.4
Inherent Viscosity	1.13
Specific Viscosity	1.59
Relative Viscosity	2.59
"K" Value	74
Heat Loss, % (maximum)	0.3
Particle Size-Sonic Sifter	
% thru 40 mesh	100
% thru 140 mesh	15
Powder Mix Time (seconds)	300
Electrical Volume Resistivity	2.0×10^{12}
Ohms/cm @ 95°C (minimum)	
Flow Time (seconds)	20
Porosity	
cc/gram	.34

Test Procedures

ASTM-D-1243
1% Cyclohexanone @ 30°C
1% Cyclohexanone @ 30°C
1% Cyclohexanone @ 30°C
BFG 793-F
BFG 812-G
BFG 488-H
ASTM-D-257-66
BFG 692-E
BFG-1094A

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