

The BFGoodrich Company  
3925 Embassy Parkway  
Akron, Ohio 44313-1799

May 20, 1991

Food and Drug Administration  
Center for Drugs and Biologics  
12420 Parklawn Drive  
Room 2-14  
Rockville, Maryland 20852

Dear Gentlereader:

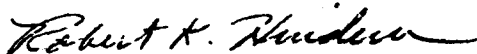
The BFGoodrich Company wishes to establish a Device Masterfile for Geon® 87390 trans 004. Geon® is a BFGoodrich brand name for polyvinyl chloride resins and compounds.

I am enclosing two copies of the composition for the above compound which is confidential business information and therefore, not subject to public disclosure under the provision of 21CFR 20.61 and 21CFR 10.111(d).

I am also enclosing two copies of a technical data sheet for Geon 87390 trans 004. Any nonclinical laboratory test which may be performed on Geon 87390 trans 004 for, or by BFGoodrich, will be performed in accordance with current FDA Good Laboratory Practice.

Sincerely,

THE BFGOODRICH COMPANY



Robert K. Hinderer, Ph.D.  
Manager, Environment, Health  
and Safety Management Systems

0520-2/jp

bcc: Mark Hross  
Dr. George Wilson  
Masterfile

BFG20988

22465001

**CONFIDENTIAL BUSINESS INFORMATION**

**GEON 87390 TRANS 004**

| <u>INGREDIENT</u>                                                                                                                                                                                                                                                                                                          | <u>WT %</u> | <u>21 CFR</u>    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|------------------|
| Polyvinyl chloride<br>(9002-86-2) <sup>a</sup>                                                                                                                                                                                                                                                                             | 83.7633     | Prior Sanctioned |
| Butadiene/methyl-<br>methacrylate/styrene<br>Copolymer (25053-09-2)                                                                                                                                                                                                                                                        | 10.0516     | 178.3790         |
| Butylacrylate/methyl-<br>methacrylate Copolymer<br>(25852-37-3)                                                                                                                                                                                                                                                            | 1.8428      | 178.3790         |
| Paraloid K-175<br>Acrylic polymer<br>(Rohm & Haas MSDS attached)                                                                                                                                                                                                                                                           | 0.9214      | 178.3790         |
| Tin Stabilizer: 8-oxo-3,5-<br>dithia-4-stannatetra-<br>decanoic acid, 10-ethyl-4,<br>4-dioctyl-7-oxo-2-ethylhexyl<br>ester [70%] (15571-58-1) and<br>8-oxo-3,5-dithia-4-stanna-<br>tetradecanoic acid, 10-ethyl<br>[(2-[(2-ethylhexyl)oxy]-2-<br>oxoethyl]thio]-4-octyl-7-oxo-,<br>ethyl hexyl ester [30%]<br>(27107-89-7) | 1.8428      | 178.2650         |
| Epoxidized soybean oil<br>(8013-07-8)                                                                                                                                                                                                                                                                                      | 0.3351      | 181.27           |
| C. I. Pigment<br>Violet 15:77007<br>(12769-96-9)                                                                                                                                                                                                                                                                           | 0.0251      | 178.3970         |

a = CAS No.

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**CONFIDENTIAL BUSINESS INFORMATION**

**GEON 87390 TRANS 004**

-2-

| <u>INGREDIENT</u>                                                              | <u>WT %</u> | <u>21 CFR</u>                                                                           |
|--------------------------------------------------------------------------------|-------------|-----------------------------------------------------------------------------------------|
| Masterbatch:                                                                   | 0.0662      |                                                                                         |
| Butadiene/methyl-<br>methacrylate/styrene<br>copolymer<br>(25053-09-2) [88.5%] |             |                                                                                         |
| Epoxidized linseed oil<br>(8016-11-3) [2.7%]                                   |             | Prior sanctioned<br>178.3140                                                            |
| Pigment blue 29<br>(57455-37-5) [8.8%]                                         |             |                                                                                         |
| Glycerol monostearate<br>(31566-31-1)                                          | 0.5863      | 175.300<br>176.200<br>also 154.1324/1505                                                |
| Mixed ester of saturated<br>fatty acids (Henkel<br>MSDS attached)              | 0.3141      | 178.3280<br>178.3690                                                                    |
| Oxidized polyethylene<br>(68441-17-8)                                          | 0.0838      | 172.260<br>175.105<br>175.125<br>176.180<br>176.200<br>176.2010<br>177.1200<br>177.1620 |
| Acrylic polymer<br>(M&T MSDS attached)                                         | 0.1675      | -                                                                                       |

22465003

BFG20990

Geon® 87390  
Food Grade Compound  
for Extrusion Blow Molding

# GEON VINYL PACKAGING COMPOUNDS

Next to your product there's nothing better

**Features** ☐ Geon® 87390 is formulated to conform to FDA regulations for food contact substances. This compound exhibits outstanding clarity, gloss, stability and blush characteristics, and is supplied in pellet form in either bags, boxes or bulk rail cars.

**Applications** ☐ Geon® 87390 is used for packages manufactured to FDA guidelines, such as edible oils, foods, cosmetics, and toiletries or any products requiring packaging to FDA guidelines.

**Processing** ☐ Geon® 87390 is easily processed at cylinder temperatures between 310°F (154°C) and 380°F (193°C). Die temperatures should be set between 350°F (177°C) and 380°F (193°C). Melt temperatures should be between 390°F (199°C) and 405°F (207°C).

## GEON® 87390 Typical Properties

| PROPERTY                                  | TEST METHOD                                          | VALUE   |
|-------------------------------------------|------------------------------------------------------|---------|
| <b>General</b>                            |                                                      |         |
| Specific Gravity                          | ASTM D-792                                           | 1.33    |
| Hardness Shore D                          | ASTM D-2240                                          | 86      |
| <b>Mechanical</b>                         |                                                      |         |
| Tensile Yield, psi                        | ASTM D-638                                           | 6,600   |
| Tensile Modulus                           | ASTM D-638                                           | 365,000 |
| Tensile Impact, ft.lbs./in²               | ASTM D-1822                                          | 75      |
| Izod Impact (1/8")<br>ft.lbs./in. notched | ASTM D-256                                           | 18.0    |
| Flexural Strength, psi                    | ASTM D-790                                           | 31,950  |
| <b>Thermal</b>                            |                                                      |         |
| Deflection Temp.<br>°C at 264 psi         | ASTM D-648                                           | 68.0    |
| <b>Optical</b>                            |                                                      |         |
| Haze (.65 mil plaque)                     | ASTM D-1003-61                                       | 5.0     |
| Transmittance %                           | ASTM D-1003-61                                       | 65.0    |
| Brabender Data<br>Equilibrium Torque      | Electric Plastograph<br>No. 6 Roller Head -<br>190°C | 1,200   |
| Stability Time -<br>Minutes               | 60 Gram Charge<br>75 RPM                             | 30'     |

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The BFGoodrich Company, Geon Vinyl Division/6100 Oak Tree Blvd., Cleveland, Ohio 44131

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Geon Vinyl Division

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March 1989

BFG20991

22465004

# GEON<sup>®</sup> PACKAGING COMPOUNDS

Next to your product  there's nothing better.

## GEON<sup>®</sup>87390 FDA Status

Geon<sup>®</sup>87390 is an octyl tin stabilized FDA acceptable compound for use in food contact applications.

Geon<sup>®</sup>87390 is composed of ingredients which meet the current requirements of the FDA for use in food contact applications when used in a manner consistent with Regulations 178.2650 and 178.3790, 21CFR. The ingredients of Geon<sup>®</sup>87390 are either listed on the following as applicable for FDA regulations, or are generally recognized as safe (GRAS), or have prior sanction for such use. Octyl tin stabilized polyvinyl chloride compounds are permitted for use in contact with food types, I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated non-alcoholic beverages), VII, VIII and IX as described in Table 1 of 21CFR 176.170.

The testing that has been performed on the compound in accordance with 178.3790 resulted in extractives well below the limitations imposed by this regulation for use conditions D, E, F and G, as described in Table 2, 21CFR 176.170.

The final food contact article must meet the extractive limitations imposed by Regulations 178.2650 and 178.3790.

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Geon Vinyl Division

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