

BFGoodrich

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

October 28, 1991

Mr. Julius Smith
Indirect Additives Branch
Division of Food and Color Additives
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, W.
Washington, D.C. 20204

Dear Mr. Smith:

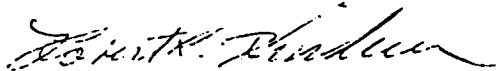
Our customer, Becton-Dickinson, has asked us to provide a copy of our confidential recipe for our product E-10 which is being considered for use in vinyl gloves.

I am enclosing two copies of the composition for the above PVC resin which is confidential business information and therefore, not subject to public disclosure under the provisions of 21CFR 20.61 and 21CFR 10.111(d). As described in the attached document, all of the ingredients function solely in the manufacture of this resin.

Please call me at (216) 374-4534, if you need any further information.

Sincerely,

THE BFGOODRICH COMPANY



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

1022-1/jp

Enclosures

Bob,

relative to the
attached... have we
received any feedback
~~disposition~~ from FDA?

Would it help for
me to call to express
our need for a response?
Joel
EX 6273

bcc: Dave Poledna

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THE BFGOODRICH COMPANY
CONFIDENTIAL COMPOSITION OF E-10

<u>Ingredient</u>	<u>Weight %</u>
Vinyl Chloride	96.8
Witcolate 4151	1.4
Lauryl/Stearyl Alcohol	0.6
Di-Octyl Adipate	0.3
Polyethylene glycol-600 MW	0.1
Drew L-140 <i>oil soluble</i>	0.2
<i>Initiator</i> Di-2-ethylhexylperoxydicarbonate (EHP) (CAS. No. 16111-62-9)	0.04
<i>Initiator</i> Alpha Cumyl Peroxyneodeconite ✓ (ACPND) (CAS. No. 26748-47-0)	0.04
<i>Initiator</i> Diisobutyl Peroxide ✓ (IBP) (CAS. No. 3437-84-1)	0.03

Geon® E-10 polyvinyl chloride resin is a water polymerized homopolymer made from vinyl chloride monomer. The ingredients used, such as dispersants and their levels, based on 100 parts monomer are:

phm

100	Vinyl Chloride
1.5	Witco 4151
0.70	L/S Alcohol
0.40	di-octyl adipate
0.20	Carbowax 600
0.30	Drew L-140
	EHP
	ACPND
	IBP

(The polymerization is exothermic. Due to changes in temperature caused by the different seasons, various combinations of the initiators, EHP, ACPND and IBP are used. A total of less than 0.1 phm total are used.)

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THE BFGOODRICH COMPANY
CONFIDENTIAL COMPOSITION OF E-10

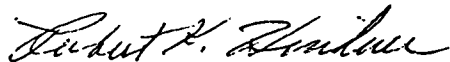
-2-

The above ingredients are added to a premix vessel along with 100 to 200 parts of demineralized water, homogenized and pumped to a reactor where the polymerization is started by raising the temperature. The polymerization temperature is approximately 106°F, but may be adjusted up or down several degrees to provide the needed end properties in the resin such as tensile strength. The reaction times vary from 6 to 10 hours with yields from 65 to 85%.

The reactions are carried out in 4300 gallon stainless steel or glass lined vessels. After the polymerization is completed, unreacted monomer is stripped from the resin. Current manufacturing regulations call for a maximum residual vinyl chloride monomer content of < 8 ppm in the resin when shipped. Residual monomer levels will be reduced further during subsequent storage and processing.

Resin is separated from the water phase by spray drying. It is packaged by automatic equipment and shipped predominately in multi-wall paper bags. All process equipment is made of stainless steel.

Contamination with other materials does not occur because the equipment is used solely to manufacture poly vinyl chloride resin. All product testing is done according to ASTM D 1755. Supervision of the process and testing is under the direction of graduate chemical engineers and chemists.



Robert K. Hinderer, Ph.D.
Manager, Health and Toxicology

Date: 10/28/91

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