



EKEF

Shintech Inc., Westayan Tower, #24 Greenway Plaza, Suite 811, Houston, Texas, 77046, (713) 965-0713

October 1, 1992

Mr. R. V. Tebbutt
The B. F. Goodrich Company
6100 Oak Tree Boulevard
Cleveland, OH 44131

*Designates
A Bottle Use*

Dear Mr. Tebbutt:

Please refer to your letter to Mr. Miki dated September 22, 1992 requesting FDA status of Shintech's PVC resin SE650A. (*Refer to AN-5465*)

All ingredients used for the production of our bottle grade resin SE650A recipe are listed and sanctioned by the FDA with the exception of initiators. The initiators are not regulated by FDA as they are consumed during polymerization and do not stay with the resin.

Please let me know if you need further information.

Very truly yours,

A. A. Reventas
Technical Director

AAR/sjn

cc: R. Miki

21592007

BFG15578

FACSIMILE MESSAGE

BFGOODRICH COMPANY
6100 OAK TREE BOULEVARD
CLEVELAND, OHIO 44131

-TEL.: (216) 447-6517
FAX: (216) 447-6459

DATE: 10/22/92 TIME: 11:20 A.M.

DELIVER TO: Ashok Shah (8-221-1875)

FAX # 8-221-1870
AVKTC
FROM: Connie Dillon (X-7831)
Leon - D/5458

MESSAGE:

attached is a draft letter
to Shintech

Total number of pages 3 including this cover letter. If all pages have not been received, please call Joanne Paige at 216/447-6278.

BFG15579

21592008

DRAFT

Mr. A. A. Reventos
Technical Director
Shintech

Dear Mr. Reventos:

In your letter dated October 1, 1992 to R. V. Tebbitt, BF Goodrich, you provided the FDA status of Shintech's PVC resin SE650A.

Would you please clarify for us if PVC resin SE 650 A (bottle grade resin) has Prior Sanction status.

In order for the PVC resin to qualify for Prior Sanction status it must meet the Current Good Manufacturing Practice (GMP) specifications. The GMP specifications 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.

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

175.105

177.1200

175.300

177.2250

176.180

179.45

177.1010

Clearance for PVC resin falls under the

BFG15580

15580 BFG

Mr. A. A. Reventar
Page 2.

"Basic Resin Doctrine" which allows the use of those things needed to manufacture the resin as long as Good Manufacturing Practices (GMP's) are followed. In evaluating the clearance of the resin, one must consider the following:

- 1) What is the intended use of the ingredient? Is its prime function to accomplish the reaction, or is it primarily intended to provide a physical property to the resin (i.e., plasticization, etc).
- 2) What is the toxicity of the ingredient? Is there an unusual or special hazard/concern.
- 3) How much is present in the recipe? As a rule of thumb, 0.5 to 1% is a gray area. Ingredient > 1% must have specific clearance and are bound by the limitations of the relevant sections. Those ingredients used ~~at~~ ^{to} 0.5% are acceptable unless they are unusually toxic.

Thanking you for your cooperation,

Sincerely

Ashok C. Shukh

BFG15581

21592010

Mr. A. A. Reventas
Technical Director
Shintech

Fax #

Dear Mr. Reventas:

In your letter dated October 1, 1992 to
Mr. R.V. Tebbutt you reported the ^{FDA} status of Shintech's
PVC resins SE 650 (A & F).

Will you please clarify for us if SE 650 A & F
meets the "Prior Sanctioned" category ~~for pre~~ and meets the
standards established under Good Manufacturing Specifications
(GMP's) for PVC resins. The current GMP's consist of maximum
volatilities of 3.0 % (1 hour at 105°C) and an inherent
viscosity of not less than 0.35 by ASTM D-1243-79.

If the PVC resin cannot meet these GMP's then it cannot be
considered "Prior Sanctioned" and is not eligible for the
broader clearances provided by this designation.

We intend to use SE 650 (A & F) resins under
broader clearance and your input ^{and clarification} will be very valuable.

Thanking you for your cooperation.

Sincerely,

Ashok C. Patel

Manus
ASSOCIATES

BFG15582

21592011

FDA, USDA, NSF, WORKSHEET

SUBJECT: Item 83741 Blk 288 (Flexible Extrusion Compound)	
Customer: Steven Kress, Action Industries (267-4750)	
DATE:	COMMENTS/STATUS:
10/14/92	Received telephone request to review Recipe on above subject for FDA Clearances. Compound to be used in vinyl weather stripping ^{on doorway} in food processing plant (USDA application)
10/19/92	Relayed FDA status via telephone to Steven Kress as follows: Compound contains 2 ingredients (P-79 & 711194) which do not have FDA clearances.

21593001

001R71 BF GOODRICH COMPANY MESSAGE SERVICE 16:25:39
FROM: P103R360 TO: CLEVMAIN DOCUMENT: 150012 48 LINES 10/15/92

ROUTE TO: DILLON, CONNIE N

GEON VINYL RESTRICTED / TECHNICAL DOCUMENT

R103360 GEON VINYL RECIPE 10/15/92 16:25:38

GEON 83741 BLACK *Pellets* LOC: 47 DEPT: 5615 ISSUE: 392
COMMODITY NO.: 83741 010 2884 EFFECTIVE DATE: 01/01/92
SBC NBR: 1311 DELETE FLAG: NO
LAB REF: CMFR:
BASED ON: *Jim Daly 8-221-1887*
APPLICATION: *I need the cubes recipe (83741 000 2880)*

PARTS	INGREDIENTS	SEQ	LOC	PERCENT
41.06776	961 000277 30 GEON RESIN	110	47	41.068
32.85420	931 00P072 PALATINOL 711 P	210		32.854
2.05338	935 00P031 EPOXY SOYA	220		2.053
.82135	714 711124 MARK 4716	310		.821
22.58726	925 00E085 CALCIUM CARBONATE	410		22.587
.41067	922 709988 RAVEN 410 BEADS	510		.411
.20533	943 00L040 PARAFFIN 165 F M.P.	610		.205
100.00000	TOTAL			100.000

SPECIFIC GRAVITY: 1.36
TYPE SAMPLE:
ISSUED:
MARKETING APPROVAL:

HARDNESS: A-72
COLOR: 2

000277: PVC Resin
(Cas. No. 9002-86-2)

* *Phth date 6-7k-11 later*
P-79: 1,2-Benzenedicarboxylic acid
DI-C7H11-Branched AN

P-31: Epoxidized Soybean Oil
(Cas. No. 8013-67-8)

* 711194: Barium - zinc stearate

F-5: Calcium Carbonate
(Cas. No. 1317-65-3)

709988: Carbon Black, Dryman Beads
(Cas. No. 1333-86-4)

L-40: Paraffin
(100%, 1474-51-4)

Lo's Station
Pier Station

None (see B30)

(11.39)

None

175.105; 176.175; 176.180;
177.120; 181.29

177.2600

172.000; 172.5710

21593002

BFG15584

21593003

UTE TO: DILLON, CONNIE N

GEON VINYL RESTRICTED / TECHNICAL DOCUMENT

03360

G E O N V I N Y L R E C I P E

10/15/92 16:25:30

ON 0374: BLACK FLT 288

LOC: 47 DEPT: 5615

ISSUE: 392

MMODIFY NO.: 0374: 010 2884

EFFECTIVE DATE: 01/01/92

=====> PROCESSING INSTRUCTIONS DO NOT EXIST FOR RECIPE (<=====

BFG15585