

BFGOODRICH

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

AN 8071
dell
✓

February 23, 1993

Carol Ruffner
Preferred Technologies
Plainwell, MI
Fax: 616/685-1148

SUBJECT: GEON 87718-004

Dear Ms. Ruffner:

Based on my review of the formulation for Geon 87718-004, all of the ingredients meet the current FDA requirements for use in contact with food. The ingredients are either listed under 21CFR Parts 172 through 184, or are prior sanctioned for use in food contact applications.

The final food contact article is subject to the following limitations:

1. Excluding food with alcohol content >8% under conditions of use of E, F, and G described in Table 2 in 21CFR 175.300(d);
2. For use in contact with food of types I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated nonalcoholic beverages), VII, VIII, and IX described in Table 1 of 21CFR 176.170(c); and
3. The final food contact article must meet the extractive limitations imposed by 21CFR 178.3790.

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

0223-3jp

bcc: Rich Kruszynski
Mary Beth Martineau - Pieth

BFG16070

21691001

FACSIMILE MESSAGE

BFGOODRICH COMPANY
6100 OAK TREE BOULEVARD
CLEVELAND, OHIO 44131

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

DATE: 2/26/93 TIME: 12:45 PM
DELIVER TO: Mary Beth Marteneau
Fax: 313-641-0915
FROM: Connie Dillon
BFG

MESSAGE:

Total number of pages 2 including this cover letter. If all pages have not been received, please call Joanne Paige at 216/447-6278.

BFG16071

21691002

FACSIMILE MESSAGE

BFGOODRICH COMPANY
6100 OAK TREE BOULEVARD
CLEVELAND, OHIO 44131

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

DATE: 2/26/93 TIME: 10:45 AM

DELIVER TO: Carol Raffner
Fax: 616-685-1148

FROM: Connie Dillon
Clev-OTM-3

MESSAGE:

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

BFG16072

21691003

I N T E R O F F I C E M E M O R A N D U M

Date: 18-Feb-1993 09:53am EDT
From: KRUSZYNSKIR
KRUSZYNSKIR@MRGATE@CLE
Dept:
Tel No:

TO: DILLON, CONNIE@A1
TO: RAMBASEK, TOM@A1
TO: MITCHELL, LANCE@A1
TO: MARTINEAU-PIELA, MARY BETH@A1

Subject: HOT LEAD!!!!

Lead Type: GENERAL INQUIRY
Leadno: 002176 Date:02151993
Contact: CAROL RUFFNER
Phone: 6166855873
Ext: 0000
Company: PREFERRED TECHNOLOGIES
Address: XXXXXXXXX
City: PLAINWELL
State: MI Zip:XXXX
Business: E Bus Segment: CUSTOM PROFILES Bus Mgr: 21F
Market: CUSTOM PROFILES Product: RIGID EXTRUSION
Application: MEDICAL FEEDER TUBES
Action taken: REFERRED CUSTOMER'S FDA INQUIRY TO TOXICOLOGY GROUP.
Details: CAROL RUFFNER HAS REQUESTED A COPY OF THE FDA APPROVAL LETTER
R 87718 TRANS. DISCUSSED WITH TOXICOLOGY GROUP FOR FOLLOW UP.
APPLICATION IS FOR HOSPITAL FEEDING TUBES.

BFG16073

21691004

0001871
FROM: P103R360
TO: DLENKAIN
RECEIVED COMPANY MESSAGE SECTION
13:58:17
02/15/93

ROUTE TO: DILLEN CONNIE N

RECEIVED TECHNICAL DOCUMENT
RECEIVED TECHNICAL DOCUMENT

02/15/93 11:58:00

COMM: 07718 TRANS PLT 004
COMMODITY NO.: 07718 000 0040
SNC NBR: 1301
LAD REF:
BASED ON:
APPLICATION:
ORMA WARNING LABEL: 4
LOC: 16 DEPT: 5131
EFFECTIVE DATE: 11/30/92
DELETE FLAG: NO
UMPR:

PARTS	INSTRUC	QTY	PRICE
100.00000	941 001046 BE450A BOTTLE RESIN	001	82.602
12.00000	942 710849 PANALOID STA 733	002	18.1035
2.20000	941 710887 METABLEN P-550	003	1.840
1.10000	941 709428 PANALOID K-175	004	1.520
2.20000	941 710887 METABLEN P-550	005	1.840
1.40000	935 001031 EPKAY 807A	006	1.234
1.03000	921 001273 VIOLET 5012 (83-12)	007	1.023
1.07900	961 000592 87640-000-4302	008	1.068
1.70000	943 710337 GLYCOLUBE 525 BEADS	009	1.085
1.37500	942 710131 LEXOL 400-7107 BEAD	010	1.214
1.30000	943 710887 METABLEN P-550	011	1.251
1.20000	941 710849 PANALOID STA 733	012	1.127
119.58400	TOTAL	100.000	

TYPE SAMPLE:
ISSUED:
MARKETING APPROVAL:
COLOR: 2

*** FOOD GRADE CLEANUP REQUIRED ***

MISC CMNT: SEE ENTERPRISE PRODUCT MANAGEMENT

FOA Clearance
710849: (BD/MMA/STY) 178.3790 (noted extraction limitations)
710883: Acrylic Processing Aid 178.3790
709120: Acrylic Polymer 178.3790
711331: Di-Octyltin Bis(isooctylmercapto) salt 178.2650 (all)
P-31: Epoxidized Soybean Oil 181.27
B-273: C.I. Pigment Violet 15 (C.I. 20.12769-96-9) 178.3790
710339: Glycol Monoacetate 178.300 (noted)
710138: Pentaerythritol adipate-stearate 178.3690 (0.4% limit)
710867: Oxidized Polyethylene 175.105/125/176.180/200/176.210/177.1200/178.1600/178.260
710540: 2-Pyrenecarboxylic acid, 2-methyl-, Butyl Ester 178.3790

BFG16074

21691005

REC'D: 02/15/93 13:50:57
 FROM: 0103R349 TO: CLEVMAIN DOCUMENT: 150009 58 LINES 02/15/93

ROUTE TO: ILLON, CONNIE N

GEON VINYL TECHNICAL DOCUMENT

RECEIVED: 02/15/93 13:50:57

GEON 87640 BLUE PWD MB 430 LSC 15 DEPT: 5137 ISSUE 008
 COMMODITY NO.: 87640 000 4302 EFFECTIVE DATE: 04/08/92
 SRC NBR: 13PM DELETE FLAG: NO
 LAB REF: CMFR: K. BRALL
 BASED ON: 87640 BLUE PMB 430. ISSUE 1. 10/93/89
 APPLICATION: BLOW MOLDING NON-TOXIC MP

PARTS	INGREDIENTS	SEQ	LSC	PERCENT
100.00000	942 710849 PARALOID 37A 733	110	10	88.45% 178.3790 ^c
3.00000	935 00P257 EPICROL 7-5	210		2.655 178.3740
10.00000	921 002272 BLUE 5006	310		9.85% 178.3970; 178.3;
113.00000	TOTAL			100.000

SPECIFIC GRAVITY: 1.43
 TYPE SAMPLE: USE PREV. SAMPLE
 ISSUED: TO ADJUST LEISOWN LEVEL.
 MARKETING APPROVAL:

PLSC CMNT: SEE PAGE 2 FOR PROCESSING & NOTES.

C RU pg 366

710849: P(BD/MMA/STY) 178.3790 ✓
 P-57: Epoxidized Linseed Oil 178.3740 ✓
 B-272: Pigment Blue 29 (C.I. 77002) 178.3297; 178.3740

BFG16076

21691007