

AN-5717
deleted

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

Date: 25-Mar-1992 07:12am EST
From: RALPH PURTELL
PURTELL, RALPH@A1@CLE
Dept: D/5373
Tel No: 216-447-6215

TO: CONNIE DILLON

(DILLON, CONNIE@A1@CLE)

Subject: Geon 180X5

The Pedricktown plant has completed some heat loss testing on newly produced Geon 180X5. A number of samples were tested at 105 deg C for one hour. All of the results were below 0.4%. (*45 3.0%*)

If there is anything else needed, please let me know.

Ralph Purtell

Connie / 3/27/92
Based on Lee's opinion
(i.e. the function of the
materials & the GMP)
this would be met
prior mentioned
criteria.
Bob

21539001

BFG14920

----- TOP -----

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

Date: 04-Mar-1992 07:29am EST
From: RALPH PURTELL
PURTELL, RALPH
Dept: D/5373
Tel No: 216-447-6215

TO: SCHILLAT, ROBERT (SCHILLATR@PED26@MRGATE)
CC: CONNIE DILLON (DILLON, CONNIE)
Subject: Geon 180X5

A customer, WRGrace, has inquired about the FDA acceptability of Geon 180X5. In order to determine Geon 180X5's FDA acceptability, we need to know the volatility of the resin.

Please have 2 or 3 retain samples of Geon 180X5 run for volatility at 105 deg. C for 1 hour.

Press RETURN to continue, GOLD MENU for options or EXIT to cancel

CC: CONNIE DILLON (DILLON, CONNIE)

Subject: Geon 180X5

A customer, WRGrace, has inquired about the FDA acceptability of Geon 180X5. In order to determine Geon 180X5's FDA acceptability, we need to know the volatility of the resin.

Please have 2 or 3 retain samples of Geon 180X5 run for volatility at 105 deg. C for 1 hour.

When the results are received, we should be able to determine the acceptability of Geon 180X5.

Let me know if there are any questions. We need the information by the end of the week.

Thanks

Ralph

----- BOTTOM -----

Press RETURN to continue, GOLD MENU for options or EXIT to cancel

BFG14921

21539002

FDA, USDA, NSF, WORKSHEET

SUBJECT: <i>Deon 180X5 Homopolymer</i>	
Customer: <i>Janice Smola - W.R. Grace & Co.</i>	
DATE:	COMMENTS/STATUS:
<i>2/19/92</i>	<i>Review above recipe for FDA status specifically 21CFR 175.300 and 177.1210</i>
<i>2/20/92</i>	<i>One of the ingredients DeonLatuf 150X21 is a copolymer (PVC & Ethyl Acrylate). It is used as a seed in its function as an initiator in the mfg. process. Since it is part of processing the resin Deon 180X5 <u>is</u> a "Homopolymer". It has clearance under 175.300 & 177.1210.</i>
<i>2/28/92</i>	<i>Per. outside counsel see Borodinsky (Keller & Hickman) Note: If in fact it was a copolymer it would have clearance under 175.300 due to the use flexibility in that it allows would allow us to look at the individual monomers (PVC & Ethyl Acrylate) which are both listed in the regulation. 177.1210 does not carry the same flexibility!</i>

21539003

BFGoodrich

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

March 3, 1992

Janice Smola
W. R. Grace & Company
55 Hayden Avenue
Lexington, MA 02173

SUBJECT: GEON 180X5 HOMOPOLYMER

Dear Ms. Smola:

At your request, we have evalutated the recipe for Geon 180X5 Homopolymer in light of the specific regulations of interest to you, namely, CFR 175.300 and CFR 177.1210. Geon 180X5 Homopolymer has FDA clearance under 175.300 and 177.1210.

If I can be of further assistance, please give me a call at 216/447-7831.

Sincerely,

THE BFGOODRICH COMPANY

Connie N. Dillon

Connie N. Dillon
Regulatory and Data System Specialist

0303-1/jp

21539004

BFG14923

FACSIMILE MESSAGE

BEGOODRICH COMPANY
6100 OAK TREE BOULEVARD
CLEVELAND, OHIO 44131

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

DATE: 3/3/92 TIME: 11:20 A.M.
DELIVER TO: Janice Smola FAX# 617/862-1982
W.R. Grace & Company
FROM: Cornie Dillon
BFG - Geon Vinyl

MESSAGE:

Attached is the FDA Status on
Geon 180X5 Homopolymer you requested.

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

21539005

BFG14924



Geon® Vinyls

BFGoodrich
Geon Vinyl Division

TEMPORARY TECHNICAL DATA SHEET

GEON DISPERSION RESIN

GEON 180X5

VINYL CHLORIDE HOMOPOLYMER

TYPICAL PROPERTIES

Appearance
* Inherent Viscosity (ASTM-D-1243-60-A)
% Moisture (Karl Fisher)
Brookfield Viscosity (RVF V20)
Yield (V2/V20)
North Fineness
Particle Size
Bulk Density
Specific Gravity

Fine white powder
0.94 ✓
0.20% maximum
50,000-60,000 cps
4:1
3.0 minimum
100% through 200 mesh screen
20-25 lbs./cu.ft.
1.40

Ralph Purcell X-625
Volatility HE 3.0%
(at 100°C)
** IV GE 0.35*
Volatility 3.0%

GENERAL QUALITIES

Medium molecular weight
Easy stir-in
Low gel temperature
Non-sagging
Good viscosity stability

RECOMMENDED USES

- Low density foam
- Expanded vinyl fabrics - foam coat, especially softer (60+ phr plasticizer) formulas where excellent overblow resistance is needed
- Thick coating applications where coating uniformity and fabric penetration is controlled by early gelation and special viscosity characteristics
- Vacuum forming
- Viscosity and yield adjustment

PACKAGING

Shipped in multiwall paper bags, net weight 50 pounds. Information shown on package includes commercial identification number, lot number, and net weight.

4/85

BFG14925

SERVICE VALUE RELIABILITY

The BFGoodrich Company, Chemical Group/8100 Oak Tree Blvd., Cleveland, Ohio 44131

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21539006

02/19/92 14:38

216 447 6262

BFG TECH SERVICE

001

THE BFGOODRICH COMPANY
GEON VINYL DIVISION
TECHNICAL SERVICE/SALES SUPPORT
6100 Oak Tree Blvd.
Cleveland, Ohio 44131

DATE:

2/19/92

TO:

Connie Ollon

COMPANY:

FROM:

Steve Allen

The following FAX contains _____ page(s)
including the cover sheet.

If you have any problems receiving this FAX, please call
216/447-7646.

FAX: 216/447-6262

21539007

BFG14926

on (80's) Hemophy m the
to a kinship m the
is used in several
data indicate a wide distribution
of its function over the monophylo
which is ~~the~~ part of the process.

~~on / 27/06/2017~~

respects

175,300 - Thick outside layer

Very Respectfully

1977/12/10 - date not 'must be'

Boyd & Boyd

and outside of \$175,300

comprados a principios

Verfahren & FA an man.

Yours Truly
John

② "No the book belongs

① we expect with $AA = \text{Chol Angles}$ you
1.75.300 pg 150

Don R. House

2021 956-5600 43474100
 2021 956-5600 43474100
 2021 956-5600 43474100

175.300 : Special Agent

Special Agent in Charge

Copy sent on envelope, dated 1/12/10

The above is to be of the
kindness of the
Agent in Charge

Letter the present in the
order

175.300 : Special Agent
The only thing
that allows the
not in fact the way to
action and the "a"
the "a" in the
appears to be

177.1210

177.1210

21539010 A

My dear brother Albert,
I am here,

~~Substance being a~~
the
from 2 cent 10/10/99
of the other way

(Handwritten notes on back of page 177B)

No. 1
Received by 218 x 177B
177/1210
No. 1
175.300
175.300
for 175.300
Not given separate copy now

001R71 BF GOODRICH COMPANY MESSAGE SERVICE 10:13:07
FROM: P103R360 TO: CLEVMAIN DOCUMENT: 200006 46 LINES 02/20/92

ROUTE TO: DILLON, CONNIE N

* GEON VINYL TECHNICAL DOCUMENT

R103360 GEON VINYL RECIPE 02/20/92 10:12:

GEON RESIN 180X5 LOC: 15 DEPT: 5162 ISSUE: S92
COMMODITY NO.: 00180 005 0000 EFFECTIVE DATE: 01/01/92
SBC NBR: 1115 DELETE FLAG: NO
LAB REF: CMFR:
BASED ON:
APPLICATION: *Does not need Prior Approval*

PARTS	INGREDIENTS	SEQ	LOC	PERCENT
93.47830	968 000039 6611 <i>PS</i>	010		88.900
.05037	953 00G135 EHP, 2 (75% IN OMS)	040		.048
3.99784	953 710716 *GEON LATEX 150X21 ✓	050		3.802
1.94275	957 710075 GRW-33X	070		1.848
.01439	951 00C038 CAUSTIC PELLETS	080	--	.014
	957 00W018 SLS SOLUTION (RESIN)	090	--	
105.15000	TOTAL			100.000

TYPE SAMPLE:
ISSUED:
MARKETING APPROVAL:

000039 *Vinyl Chloride*
G-135 *Dil (2-Ethyl Hexyl) Peroxydicarbonate*
It is used in mfg process 75% Pure in OMS
on instruction in mfg process
copolymer
49% Polymer
1.5% SBC
49.4% water
contains comp w/84
710716 *PVC Polymer w/water *Ethyl Acrylate/VC*
710075 *Lauryl Stearyl Alcohol Blend Natural Based*
C-38 *Sodium Hydroxide Pellets NF Grade*
W-18 *Sodium Lauryl Sulfate, 30% Solution*

*Residual VC
is 50 ppb (normal is
20 ppb)
per Bst Compall
001500 210000

21539011

BFG14931

ROUTE TO: DILLON, CONNIE N

* GEON VINYL TECHNICAL DOCUMENT *

R103360

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

02/20/92 10:12:

GEON RESIN 180X5

LOC: 15 DEPT: 5162

ISSUE: S92

COMMODITY NO.: 00180 005 0000

EFFECTIVE DATE: 01/01/92

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

21529012

BFG14932

3R60
 M10360
 PRODUCT NO. 00150 021 0000 LOC 10 DEPT 2441 ISSUE S92
 DESCRIPTION GEON LATEX SBC 5211 INT. RM. 965000189

PRODUCTION RECIPE INQUIRY
 SPECIALTY POLYMERS AND CHEMICALS

PAGE 1

USERID: N55CND1A
 TERMID: PTE0041

CO. CODE P

ITEM	RM NUMBER	DESCRIPTION	QUANTITY	USE
010	955 710720	VCM ✓	98.872800	
020	952 00D087	SODIUM PERSULFAT	.431400	
030	957 00W084	AOS (FOR LATEX) <i>prop</i>	5.925200	
040	952 00D009	TSPP	.328600	
050	951 00C012	AMMONIA-AQUA	1.189000	
060	951 00C047	CAUSTIC SODA 50%	.100000	
070	955 00M069	ETHYL ACRYLATE ✓	.253800	
080	957 00W058	ANIONIC SURFACTA	.122200	
090	957 00W059	SODIUM LAS SLURR	.107800	

TOTAL 107.330800 TO MAKE 100.000000

END OF INQUIRY

*emulsion polymer
 seed process
 VCM/EA copolymer
 VCM polymer*

21539013

BFG14933