

AN 4529
deleted

June 21, 1991

Dave Polenda

SUBJECT: GEON 121X10/FDA 20CFR 177.2600

Recently you asked whether Geon 121X10 was acceptable under 177.2600 and sent me a copy of Wally Bachtel's letter dated 10/16/86. In order to resolve some of the issues we discussed, I called Leo Borodinsky at Keller & Heckman for guidance.

As you know, PVC is prior sanctioned and also is specifically listed under a number of sections (see RKH letter 5/13/91, attached). Clearance for PVC resin falls under the "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).
- 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 clearances and are bound by the limitations of the relevant sections. Those ingredients used at <0.5% are acceptable unless they are unusually toxic.

Based on our discussions, the recipe that Wally reviewed (10/16/86) contained 0.25% di-(C₇ and C₉ Alkyl) adipate. Although some might argue that Wally's opinion is somewhat conservative, I believe that it was reasonable considering concerns about plasticizers.

With the above information in mind, your present goal of producing a Geon 121X10 type resin which meets 177.2600 can be achieved by either, 1) reducing the level of the di-(C₇ and C₉ Alkyl) adipate to <0.1% as long as its primary function is to facilitate the reaction, or, 2) changing to DOP (not to exceed 30% by weight).

R. K. Hinderer/jp
Robert K. Hinderer

0621-2/jp
cc: Bob Campbell
Connie Dillon
Mark Hross

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BFGoodrich

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

May 13, 1991

Mr. Michael Becker 788-317-3040
Clintec
3 Parkway, North
Suite 200
P. O. Box 760
Deerfield, IL 60015-0760

SUBJECT: PVC RESIN FDA STATUS

Dear Mr. Becker:

At your request, I am writing to you regarding the FDA status of Geon 110X500. Polyvinyl chloride is prior sanctioned for use in general food contact applications, both flexible and rigid. The prior sanction is based on an article by A. J. Lehman, from the FDA, published in the Journal of the Association of Food and Drug Officials, July, 1951. The current Good Manufacturing Practice (GMP) specifications for prior sanctioned PVC 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 21CFR:

175.105	177.1200
175.300	177.2250
176.180	179.45
177.1010	

If you have any further questions, please call me at 216/374-4534.

Sincerely,

THE BFGOODRICH COMPANY

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

0513-1/jp

cc: Mark Hross

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BFGoodrich

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

AN 4528
dated

June 25, 1991

Dr. George Wilson
Food and Drug Administration
Center for Drugs and Biologics
Central Document Room
12420 Parklawn Drive
Room 2-14
Rockville, Maryland 20852

SUBJECT: MAF Number Assigned: MAF-369
Date of Submission: May 20, 1991
Title of Submission: Geon 87390 trans 004
Holder of Submission: BFGoodrich
Submitted By: BFGoodrich
Agent(s): None

Dear Dr. Wilson:

This letter is the FDA's authority to refer to MAF-369 for the information contained therein on Geon 87390 trans 004 in the review of any of your premarket approval applications (PMA's), investigational device exemptions (IDE's), premarket notification submissions, reclassification petitions, color additive petitions, or other submissions to the FDA. You should include the original copy of this letter in the original copy of your submission to the FDA in order that your submission will not be found deficient for the lack of authorization and to expedite processing.

Any Geon 87390 trans 004 supplied to you for this purpose will comply with the product specifications contained in MAF-369.

Sincerely,

THE BFGOODRICH COMPANY

Robert K. Hinderer/jp

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

RKH/jp

cc: Mark Hross

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JUN 14 1991

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June 13, 1991

To : J. Edward Fattlar
From: Lance A. Mayer

Re: ~~J~~DAP Extractions

cc: Keith L. Gardner
Bob K. Hinderer
Bernie C. Knoble
Bud Pazur

Ashok Shah
D'Lane L. Wisner
Roman W. Wypart
File

Summary: Higher than normal conversion Geon 3400 was used to make a "Mystique" bottle compound with 25 parts of Geon 3400. The bottles were extracted with both 8% ethanol in water and 50% ethanol in water. No residual DAP was found in the extract. The test had a detection limit of 50 parts per billion (ppb).

Discussion: In order to get FDA approvability for the "Mysitic" resins, the resin was modified to obtain a lower residual diallyl phthalate (DAP) level. The modification involved running the reaction to a 15 psi pressure drop rather than the usual 3 psi pressure drop. This was expected to increase the conversion approximately 5%. In the one polymerization made under these conditions, the extra 12 psi pressure drop took one hour to obtain.

A sample of the slurry was obtained and dried in the dryer at the Technical Center. The resin was then compounded by Roman Wypart into the 87536 formulation using 25 parts of Geon 3400 rather than the conventional 20 parts used in the current "Mystique" compound. Earl Price then blowmolded the 12 ounce bottles from this compound to be used in the extraction study.

Brenda Bennett then extracted the bottles using 8% ethanol and 50% ethanol to simulate contact with aqueous foods and alcoholic foods following the protocol in "Guidelines for Migration Studies for FDA Acceptance of Indirect Food Additives" by Wellman C. Bachtel, January 29, 1990. These extractions extended over the course of 10 days. For the first two hours the bottles were stored in a convection oven at 150°F. For the rest of the time the temperature was maintained at 120°F. Samples were removed from the three bottles at 2, 8, 24, 48, 96 and 240 hours.

A modification of Dave Ernes's procedure was initially used. This new procedure involved the evaporation of the water and ethanol, re-dissolution in acetonitrile and then analysis via high pressure liquid chromatography. This produced acceptable results in the validation study of the 50% ethanol/water (see Table 1). However, it was discerned that in the samples that were allowed to evaporate overnight (namely the 8% ethanol), an appreciable amount of the DAP also evaporated. This was despite its very low vapor pressure of

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about 0.001 mm Hg at ambient temperature. (The vapor pressure of water at 70°F is 18.8 mm Hg).

A procedure was then developed that permitted the analysis of the extract directly. (This approach had been abandoned earlier because of the interference of the methanol that was in the ethanol.) This gave acceptable results in the validation, (see Tables 2 and 3).

Experimental: Calibration standards were prepared by dilution of DAP into both 8% and 50% ethanol solutions. Standard curves were prepared based on peak height (see Figures 1 and 2). Peak height correlated better than area due to baseline determination.

Prior to injection, the extracts were filtered through a 0.45 μ Gelman filter. The following chromatographic conditions were used:

Column:	Varian Reverse Phase C18, MCH-NCAP-5 μ
Mobile phase:	45/55 acetonitrile/water
Flow rate:	1.8 ml/min
Injection Vol:	20 μ l
Detection:	UV at 220 nm.

Figure 3 is the chromatogram of a direct injection of 50% ethanol. Figure 4 shows the chromatogram of a direct injection of the 240 hour extraction sample of a bottle (no peak attributed to the DAP). Figures 5, 6 and 7 show the validation chromatograms where the 240 hour extract sample was spike with 50, 100 and 150 ppb of DAP to determine the recovery percentage. The peak attributed to the DAP had a retention time of ~6.3 minutes. Figures 8 through 12 show similar chromatograms for the 8% ethanol.

Conclusions:

- Geon 3400 should be FDA approvable where the contents are 0 to 50% ethanol in water or for contact with fatty foods.
- Since the amount of time required for the extra 12 psi pressure drop was inordinately long (an extra hour of polymerization time), the polymerization should be repeated. If it remains this long, the initiator system should be reviewed as well as the possibility of repeating the extraction on normal Geon 3400.

Acknowledgments: I am indebted to:

Brenda Bennet for her expeditiously getting this testing done;
Daren Whetstone for arranging the polymerization and obtaining the resin;
Roman Wypart and Earl Price for making the compound and bottles; and

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Table 1
Percent Recovered from 50% Ethanol/Water Extract
Evaporation Technique

ppb	Results			Average
150	82.3	84.8	84.8	84.0
100	98.8	79.9	89.4	89.4
50	103	65.3	65.3	77.9

Table 2
Percent Recovered from 50% Ethanol/Water Extract
Direct Analysis Technique

ppb	Results			Average
150	99.4	94.4	99.4	97.7
100	74.4	104.3	104.3	94.3
50	74.0	74.0	59.1	69.0

Table 3
Percent Recovered from 8% Ethanol/Water Extract
Direct Analysis Technique

ppb	Results			Average
150	84.9	90.0	100.1	91.7
100	73.8	86.4	79.0	79.7
50	84.0	98.8	83.9	88.9

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Figure 1

DAP CALIBRATION in 8% EtOH

June 11, 1991

Brenda Bennett

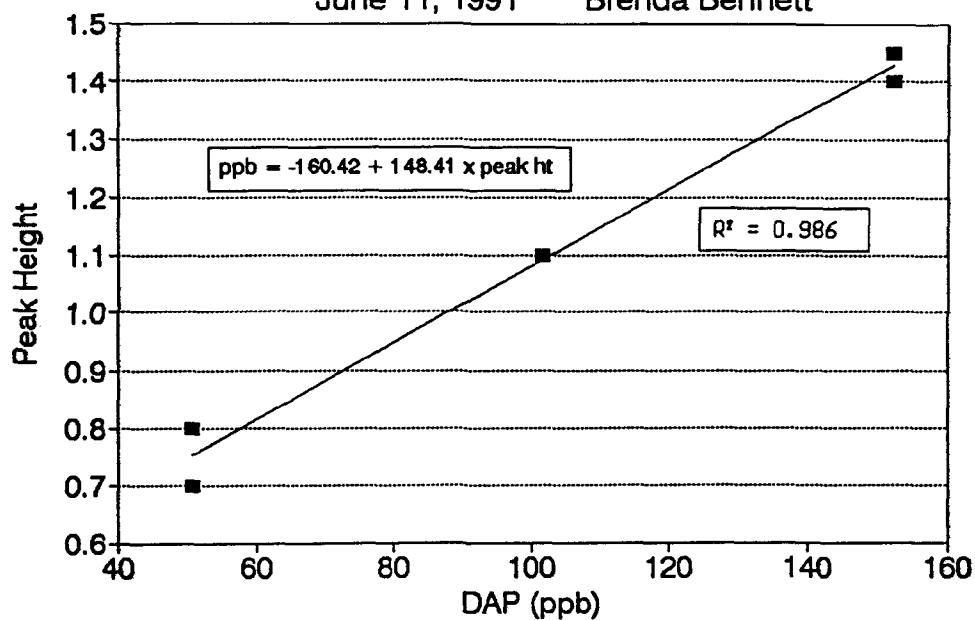
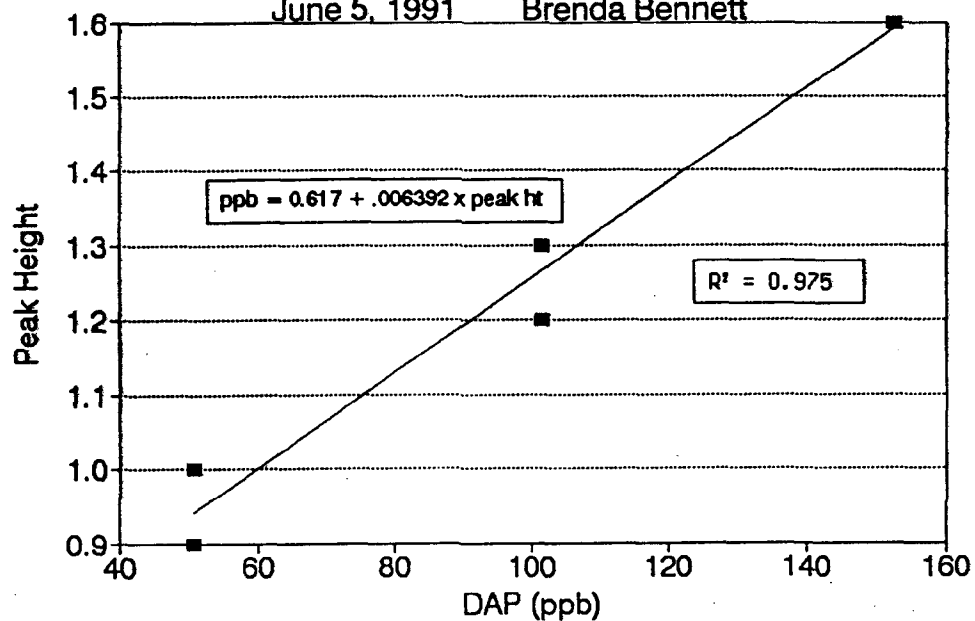


Figure 2

DAP CALIBRATION

June 5, 1991

Brenda Bennett

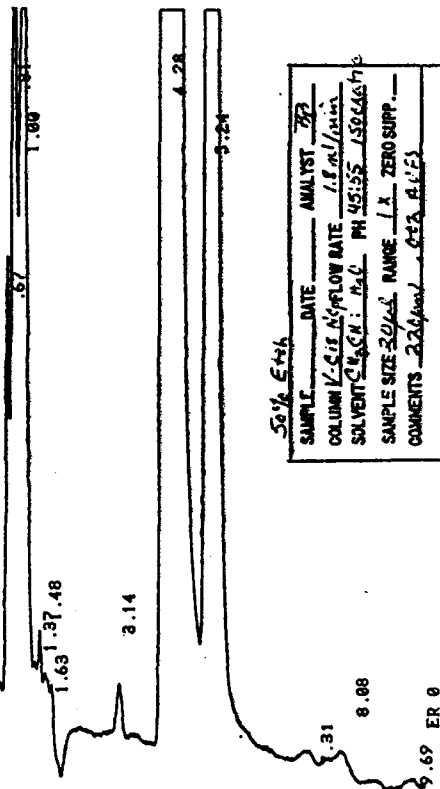


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FIGURE 3

CHANNEL A INJECT 06/04/91 09:43:50 STORED TO BIN # 88



DATA SAVED TO BIN # 88

DAP EXTR @ 50% RETENTION 06/04/91 09:43:50 CH= "A" PS= 1.

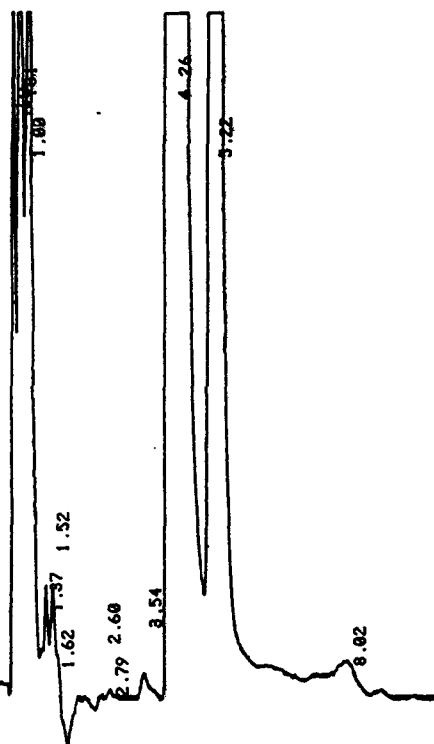
FILE #. METHOD 0. RUN 87 INDEX 26 BIN 88

PEAKS	HTX	RT	PK	HT	BC
1	0.792	0.67	571	02	
2	1.42	0.81	1024	02	
3	1.595	1.1	1085	02	
4	0.192	1.37	139	02	
5	0.123	1.48	96	02	
6	0.126	1.63	91	03	
7	0.885	3.14	61	01	
8	88.891	4.28	64888	08	
9	6.78	5.24	4888	05	
10	0.021	7.31	15	02	
11	0.042	8.08	30	03	
12	0.013	9.69	9	01	
TOTAL	100		72897		

WARNING - MEMORY AT 1. K - UNPROTECTED CHROMATOGRAMS WILL BE REPLACED

FIGURE 4

CHANNEL A INJECT 06/04/91 13:00:09 STORED TO BIN # 100



DATA SAVED TO BIN # 100

DAP EXTR @ 50% VALIDATION 06/04/91 13:00:09 CH= "A" PS= 1.

FILE #. METHOD 0. RUN 99 INDEX 38 BIN 100

PEAKS	HTX	RT	PK	HT	BC
1	1.46	0.68	1013	02	
2	1.502	0.81	1043	02	
3	1.418	1.1	964	02	
4	0.246	1.37	171	02	
5	0.25	1.52	173	02	
6	0.127	1.62	88	03	
7	0.023	2.6	16	02	
8	0.021	2.79	15	03	
9	0.04	3.54	28	01	
10	89.167	4.26	61888	08	
11	5.709	5.22	3943	05	
12	0.036	8.02	25	01	
TOTAL	100		69487		

WARNING - MEMORY AT 0. K - UNPROTECTED CHROMATOGRAMS WILL BE REPLACED

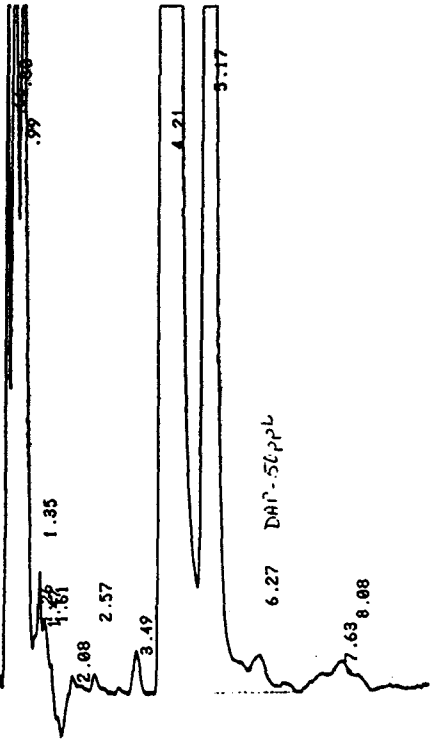
WARNING - MEMORY AT 0. K - UNPROTECTED CHROMATOGRAMS WILL BE REPLACED

2000 50ppb - 5000 EXR

FIGURE 5

Validation #3 spiked 50ppb DAP

CHANNEL A INJECT 06/04/91 15:03:24 STORED TO BIN # 103



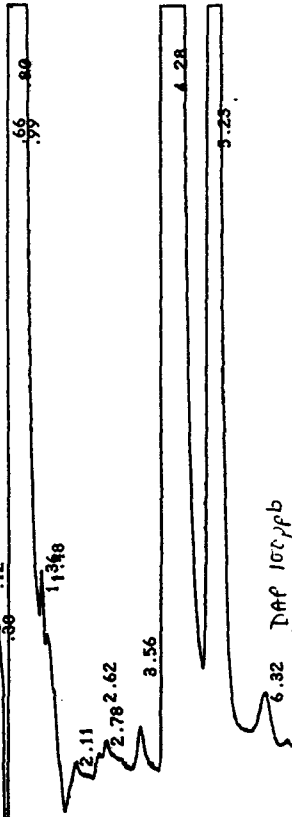
DATA SAVED TO BIN # 103

DAP EXTR @ 50% VALIDATION									
FILE #	METHOD	HTX	RT	RUN	PK	HT	BC	INDEX	BIN
1	1.34	0.66	0.66	896	02			41	103
2	1.503	0.8	1.005	02					
3	1.468	0.99	981	02					
4	0.14	1.26	93	02					
5	0.263	1.35	176	02					
6	0.179	1.47	120	02					
7	0.104	1.61	69	03					
8	0.104	2.08	69	02					
9	0.092	2.57	51	02					
10	0.092	3.49	61	03					
11	89.665	4.21	59960	08					
12	4.937	5.17	3301	05					
13	0.046	6.27	31	01					
14	0.032	7.53	22	02					
15	0.052	8.08	35	03					
TOTAL									66871

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Validation #5 spiked 100ppb DAP
CHANNEL A INJECT 06/04/91 16:22:41 STORED TO BIN # 105

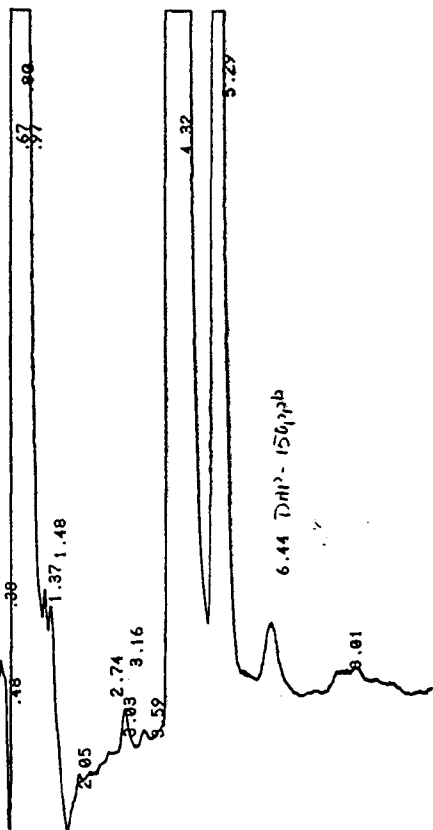


DATA SAVED TO BIN # 105

DAP EXTR @ 50% VALIDATION									
FILE #	METHOD	HTX	RT	RUN	PK	HT	BC	INDEX	BIN
1	0.106	0.12	77	01				43	105
2	0.478	0.38	347	01					
3	2.697	0.66	1976	02					
4	2.523	0.8	1848	02					
5	2.264	0.99	1659	02					
6	0.688	1.36	504	02					
7	0.484	1.48	355	02					
8	0.106	2.11	77	03					
9	0.04	2.62	29	02					
10	0.058	2.78	43	02					
11	0.076	3.56	56	03					
12	85.672	4.28	62763	08					
13	4.696	5.23	3440	05					
14	0.08	6.32	59	01					
15	0.037	8.1	27	01					
TOTAL									73259

WARNING - MEMORY AT 2. K - UNPROTECTED CHROMATOGRAMS WILL BE REPLACED

Validation #9 spiked 150ppb DHP
CHANNEL A INJECT 06/05/91 11:21:35 STORED TO BIN # 111



DATA SAVED TO BIN # 111

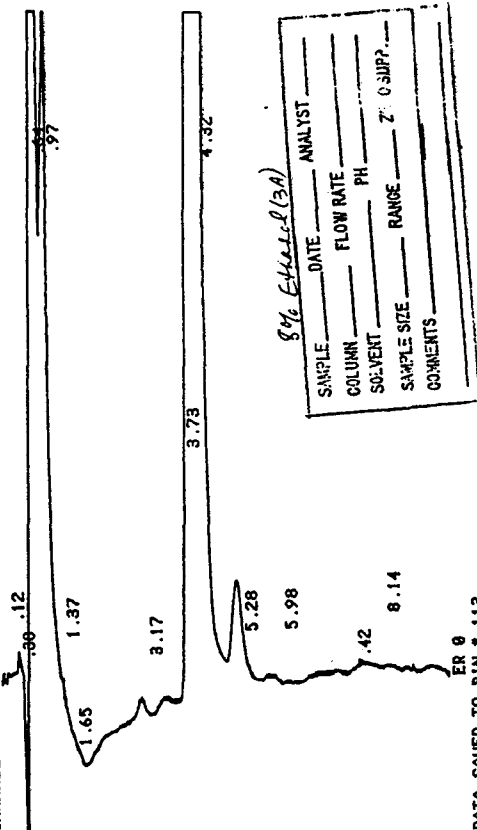
DAP EXTR @ 50% VALIDATION 06/05/91 11:21:35 CH= "A" PS= 1.
FILE 8. METHOD 0. RUN 110 INDEX 49 BIN 111

PEAK#	HTX	RT	PK	HT	BC
1	0.163	0.38	107	02	
2	0.334	0.48	219	03	
3	3.295	0.67	2157	02	
4	3.132	0.8	2051	02	
5	2.668	0.97	1747	02	
6	0.521	1.37	341	02	
7	0.46	1.48	301	02	
8	0.837	2.05	24	03	
9	0.02	2.74	13	02	
10	0.031	3.03	20	02	
11	0.098	3.16	64	02	
12	0.033	3.59	21	02	
13	85.575	4.32	56024	08	
14	3.466	5.29	2269	05	
15	0.126	6.44	83	01	
16	0.041	8.01	27	01	
TOTAL	100.		65468		

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CHANNEL A INJECT 06/05/91 12:14:21 STORED TO BIN # 113



DATA SAVED TO BIN # 113

DAP EXTR @ 50% VALIDATION 06/05/91 12:14:21 CH= "A" PS= 1.
FILE 8. METHOD 0. RUN 112 INDEX 51 BIN 113

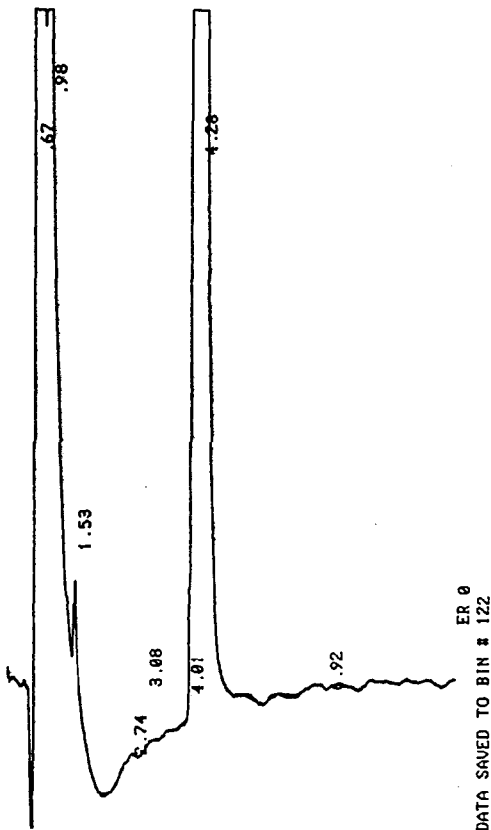
PEAK#	HTX	RT	PK	HT	BC
1	0.575	0.12	72	02	
2	1.682	0.38	211	03	
3	14.371	0.64	1800	02	
4	8.687	0.97	1088	02	
5	1.192	1.37	149	02	
6	0.192	1.65	24	03	
7	0.271	3.17	34	02	
8	0.154	3.73	19	02	
9	71.718	4.32	8983	08	
10	0.947	5.28	119	05	
11	0.067	5.98	8	01	
12	0.077	7.42	10	02	
13	0.067	8.14	8	03	
TOTAL	100.		12525		

WARNING - MEMORY AT 0. K - UNPROTECTED CHROMATOGRAMS WILL BE REPLACED
INK LOW - CHANGE PRINT CARTRIDGE AND PRESS [CTRL-SHIFT-C]

84% Extracted (3M)

SAMPLE	DATE	ANALYST
COLUMN	FLOW RATE	
SOLVENT	PH	
SAMPLE SIZE	RANGE	2" 0 SUP?
COMMENTS		

FIGURE 7
 5-1 A40624 + Mynstique 8% Extra Extr
 CHANNEL A INJECT 06/05/91 14:17:51 STORED TO BIN # 122



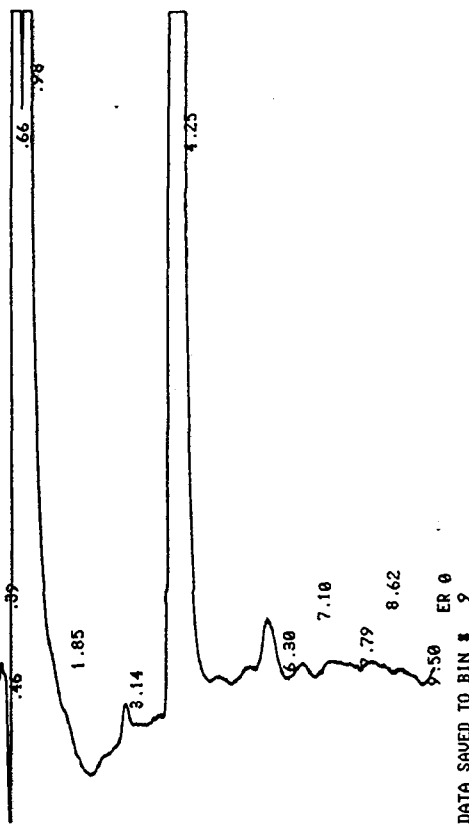
DAP EXTR @ 50% VALIDATION 06/05/91 14:17:51 CH= "A" PS= 1.
 FILE 8. METHOD 0. RUN 121 INDEX 60 BIN 122

PEAK#	HTX	RT	PK	HT	BC
1	29.174	0.67	3957	02	
2	9.279	0.98	1259	02	
3	2.202	1.53	299	03	
4	0.246	2.74	33	02	
5	0.216	3.08	29	02	
6	0.265	4.01	36	02	
7	58.544	4.28	7941	03	
8	0.074	6.92	10	01	
TOTAL	100.		13565		

WARNING - MEMORY AT 0. K - UNPROTECTED CHROMATOGRAMS WILL BE REPLACED
 INK LOW - CHANGE PRINT CARTRIDGE AND PRESS [CTRL-SHIFT-C]

FIGURE 10

Validation # 7 8% Extra Spiked @ 150,000
 CHANNEL A INJECT 06/11/91 11:16:33 STORED TO BIN # 9

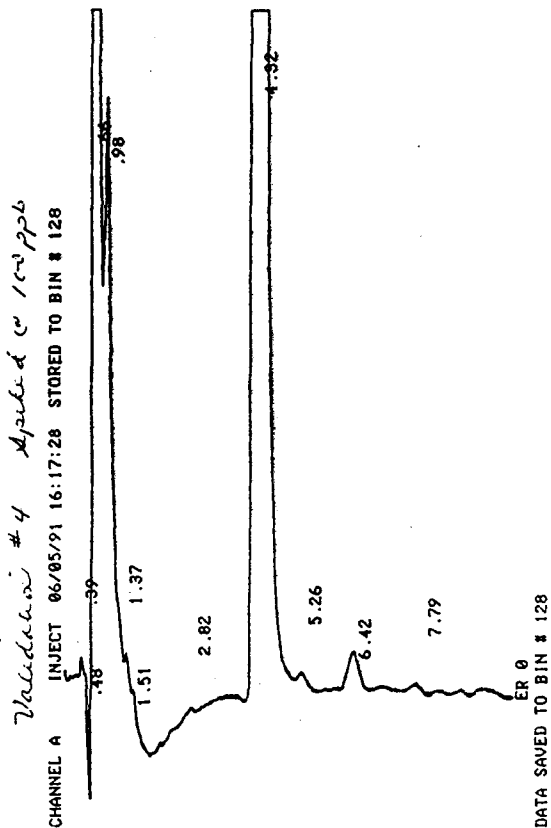


DAP EXTR @ 8% VALIDATION 06/11/91 11:16:33 CH= "A" PS= 1.
 FILE 8. METHOD 0. RUN 136 INDEX 75 BIN 9

PEAK#	HTX	RT	PK	HT	BC
1	0.697	0.39	77	02	
2	1.537	0.46	171	03	
3	17.654	0.66	1960	02	
4	18.663	0.98	2072	09	
5	0.576	3.14	64	05	
6	59.293	4.25	6583	01	
7	0.724	6.3	80	02	
8	0.231	7.1	26	02	
9	0.261	7.79	29	02	
10	0.267	8.62	30	02	
11	0.096	9.5	11	03	
TOTAL	100.		11102		

WARNING - MEMORY AT 0. K - UNPROTECTED CHROMATOGRAMS WILL BE REPLACED
 INK LOW - CHANGE PRINT CARTRIDGE AND PRESS [CTRL-SHIFT-C]

FIGURE 11

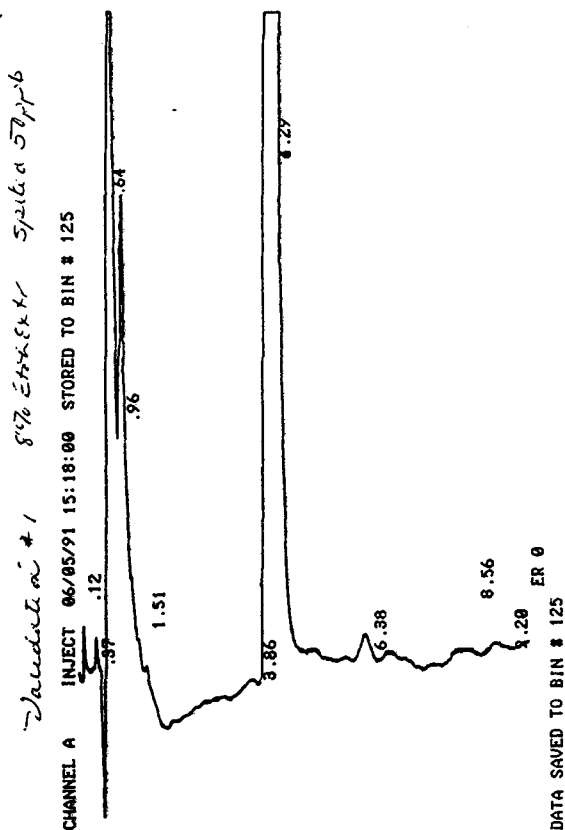


5%
DAP EXTR 0.50% VALIDATION 06/05/91 16:17:28 CH= "A" PS= 1.

FILE	8.	METHOD	0.	RUN	127	INDEX	66	BIN	128
PEAK#	HTX	RT	PK	HT	BC				
1	0.529	0.39	72	02					
2	0.959	0.48	131	02					
3	19.697	0.66	2683	02					
4	6.559	0.98	893	02					
5	1.175	1.37	160	02					
6	0.685	1.51	93	03					
7	0.223	2.82	31	02					
8	69.625	4.32	9483	03					
9	0.117	5.26	16	01					
10	0.362	6.42	49	01					
11	0.066	7.79	9	01					
TOTAL	100.		13620						

WARNING - MEMORY AT 2. K - UNPROTECTED CHROMATOGRAMS WILL BE REPLACED
INK LOW - CHANGE PRINT CARTRIDGE AND PRESS [CTRL-SHIFT-C]

FIGURE 12



5%
DAP EXTR 0.80% VALIDATION 06/05/91 15:18:00 CH= "A" PS= 1.

FILE	8.	METHOD	0.	RUN	124	INDEX	63	BIN	125
PEAK#	HTX	RT	PK	HT	BC				
1	0.592	0.12	67	01					
2	1.219	0.37	137	02					
3	17.664	0.64	1989	02					
4	6.725	0.96	757	08					
5	0.178	1.51	20	03					
6	0.124	3.86	14	02					
7	72.995	4.29	8221	03					
8	0.302	6.38	34	01					
9	0.124	8.56	14	02					
10	0.077	9.2	9	03					
TOTAL	100.		11262						

WARNING - MEMORY AT 1. K - UNPROTECTED CHROMATOGRAMS WILL BE REPLACED
INK LOW - CHANGE PRINT CARTRIDGE AND PRESS [CTRL-SHIFT-C]

BFGoodrich

The BFGoodrich Company

3925 Embassy Parkway
Akron, Ohio 44333-1799

FAX: 216-374-2333 1st Floor
216-374-2238 2nd Floor
216-374-3338 3rd Floor
216-374-3456 Legal

DATE: June 4, 1991

TO: Chuck Purks PHONE: Fax: 933-1678
ALTC

NUMBER OF PAGES: 1 (INCLUDING COVER PAGE)

COMMENTS:

RE: GEON 86155 TRANS 0025

Please check the following:

- 1) I cannot confirm that Synpron 221 is FDA acceptable. I cannot find trisnonylphenyl phosphite in any of the sections quoted: 181.29, 181.27, 178.2010. The supplier should be asked under what section(s) would Synpron 221, and not the individual components, be cleared. Also, under what section is TNPP cleared?
- 2) The supplier for PO57 does not list 181.27, a Prior Sanction for EPLSO. Does this product meet 21CFR specs: iodine number maximum 6; oxirane oxygen, minimum 6 percent? Will they certify that it meets 21CFR 181.27?

FROM: Bob Hinderer PHONE: 374-4534
BFGoodrich - Corporate

4/91 JJP

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