

AN 4562
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March 12, 1990

Daphene Benderly
ALTC

11
SUBJECT: (FDA STATUS - PVC COMPOUNDS)

(Compounds 165-46-21-1,2)

FDA has canceled the provisional listing for FD&C, Red #3, the colorant in 85435, Red MB 702. If this colorant is replaced with an acceptable one, these compounds would be acceptable for use in contact with foods of high water content only.

(Compound 165-46-25-1)

Compound 165-46-25-1 meets the current requirements of the FDA for use in contact with foods of high water content only. The ingredients in this compound are either listed on an appropriate regulation, or are generally recognized as safe (GRAS) or prior sanctioned for such use.

(Compounds 165-46-24-1,2)

Providing these compounds meet the definition (ASTM) of a rigid or semirigid PVC, they meet the current requirements of the FDA for use on contact with foods of high water content only, except liquid milk, malt beverages and carbonated nonalcoholic beverages. The ingredients in these compounds are either listed on an appropriate regulation, are generally recognized as safe (GRAS), or prior sanctioned for such use. The end food contact article must meet the extractive limitations imposed by 21CFR 178.2650 "Organotin Stabilizers In Vinyl Chloride Plastics".

Good-Rite^(R) 2601X120 would be acceptable for use in vinyl compounds, providing it can meet the extractive limitations of 177.1010 or 178.3790.



W. C. Bachtel

WCB/jp

cc: Cheryl Brubaker - CL-OTM-3
Carol Schmidt - CL-OTM-3
Ken Sraill - ALTC

20839001

BFG07400

BFGoodrich**INTER-ORGANIZATION CORRESPONDENCE**

TO	Wally Bachtel	FIELD POINT OR DEPT. & BLDG. NO. Bach	DATE YOUR LETTER
FROM	Daphne Benderly	FIELD POINT OR DEPT. & BLDG. NO. 5052	DATE THIS LETTER 2/27/90
SUBJECT			

FDA Status

I am planning to commercialize several materials in the near future, and would like to confirm that they are FDA acceptable. I have enclosed the recipes for the compounds:

165-46-21-1

165-46-21-2

165-46-24-1

165-46-24-2

165-46-25-1

I would also like to know if the use of Goodrite 2601x120 process aid (BFG code 941710961) is acceptable in FDA compounds.

2601:120 = 147LW264124

Thank you!

*2600 x 424
02600 424 000 Daphne Benderly
PK 178.3790
177.1010*

cc: Cheryl Brubaker
Carol Schmidt
Ken Srail

cmpds.fda

20839002

BFG07401

Basdire 2601 X120

Nycan 02600 424 0000

Nycan 26424

W-37 -	SLS	9.571
m-8	ethyl acetate -	1.54
m-9	methyl methacrylate	85.757
D-1	Soda Ash	0.189
D-87	Sodium peracetate	0.094
G-136	T BHP	0.0529
G-40	SFS	0.145

OK. 178.3790
178.1010

20839003

BFG07402

DATE 8/9/90

PROB. NO.

SUBJECT OF EXPT

86318, 86319

See pg 7

Scale up w/ 1827 phr DOP

0045 color package?

①

②

	%		%
Geon 36	20.175100	→	12.9.94
P31	2.01810	→	1.4% oxidized say brownish
P75	12.0328	→	12.5% DOP
P47	1.01810	→	6.99 DOP B&H Adipic
K120ND	1.4042	→	1.40
T110612	0.175 (0.25)	→	.175 Polyethylene 742 - highly indurated
L22	0.175 (0.25)	→	.175 stearic acid
Synpro 1795	0.7021	→	.699 Ca/2m Stearate
S82	0.7021	→	.699 Zinc, monophenyl phosphite

85367 0004302	0.39	→	.292 1101377-92	P257m	ultrafine blue - 5
15435 Add MB 202MB	0.097	→	.068 1101377-89.7	P257-10.26	Red 13 2.5% 7/10/98

142.987

165-46-21-1,2

EXPERIMENTER

DATE

WITNESS

DATE

20839004

BFG07403

B. F. GOODRICH COMPANY

DATE 2.11.4/90

PROB. NO.

SUBJECT OF EXP'T Superplastics

Modify 165-19-137-4 by using Gen 31 (for 10x4) and 710754 (for Citratex A 4)

DIOP

1/6 ①

Gen 31 42.974 00

P 3 4.297 10

V120ND 0.859 2

710754 56.581 20

S 81 0.086 0.2

L 22 0.086 0.2

710612 0.086 0.2

L 3 0.043 0.1

710858 0.0004 0.001

832.701

Diisotyl phthalate - fixed high of high water content of

zinc stearate

potassium acid

Amalake 742

calcium stearate

Vanillin

165-40-25-1

20839005

EXPERIMENTER

DATE

WITNESS

DATE

BFG07404

DATE 2/14/90

PROB. NO.

SUBJECT OF EXPT

Avionics

Increase flow of 86403- replace G 264110x902

①

②

%

Geon 26

100

80.483

-

110x902

-

100

P 75

13

10.463

→

DOP

P 31

5

7.024

→

Epoxy 6000

709256

3

2.414

→

K120MD

710888

3

2.414

→

Adhesive T-PA1753

710811

0.01

0.008

→

Ultramarine black

85367000 4202

0.04

0.032

→

ultramarine blue

L 21

0.2

0.161

→

Stearic acid

124.25

165-46-24-1,2

20889006

EXPERIMENTER

DATE

WITNESS

DATE

BFG07405