BFGoodrich **INTER-ORGANIZATION CORRESPONDENCE**

TO	FIELD POINT OR DEPT. & BLDG. NO.	DATE YOUR LETTER
R.K. Hinderer	BATH/0020 SEP 26 1991	
FROM	**FIELD POINT OR DEPT. & BLDG. NO.**	**DATE THIS LETTER**
Dave Poledna	ALTC/5057	9/24/91

SUBJECT

E-10 RECIPE FOR SUBMISSION TO FDA

We are in the process of developing a recipe for use in vinyl gloves acceptable under 21 CFR177.2600. The customer is Becton-Dickinson. The recipe is based on our current Geon® 121X10 recipe. Based on the opinions of W.C. Bachtel[1,2] initially, and you[3], Geon® 121X10 cannot be represented as being FDA acceptable. The recipe was modified so that the product would be acceptable under the previously mentioned paragraph of the Code Of Federal Regulations.

From the stand point of manufacturing the product, it would be good to have some recipe flexibility. I propose that we list ingredient maximum levels in our letter to the FDA. The following would be reasonable maximums, assuming of course, that we do not exceed an allowable resin extract requirement.

PROPOSED PHM	
1.50	Witco 4151 (proprietary surfactant blend)
0.70	L/S Alcohol blend
0.40	Di octyl adipate
0.20	polyethylene glycol 600 molecular weight (Carbowax 600)
0.30	Drew L140 (proprietary defoamer blend)

We should retain the flexibility to use diisobutyryl peroxide (IBP) in combination with either or both EHP and ACPND. The IBP is a very fast initiator and would be beneficial for productivity, if we can keep it from decomposing in the premix and starting polymerization prematurely.

Similarly, we might like to be able to use an FDA acceptable defoamer to improve performance during stripping. We are currently evaluating the effect of defoamer added after polymerization, but before recovery on the amount of foam carried over and on residual vinyl chloride monomer (RVCM) levels in the slurry.

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[1]BFG IOC "GEON121X10 - ABEX 33S" by W.C. Bachtel 4/9/87

[2]BFG IOC "GEON 121X110 - FDA STATUS" by W.C. Bachtel 10/16/86

[3]Personal Communication from R.K. Hinderer to Dave Poledna "GEON 121X10/FDA 21CFR 177.2600" 6/21/91

E10_RECIPE_FDA_RKH_9-91

Attached are claims from Witco (4151), Monsanto (DOA) and Drew (Drew L-140) that their products meet the requirements of 21 CFR177.2600, as well as copies of letters sent to Witco and Drew asking them to disclose the structures of their products to FDA. Witco and Drew are in the same situation as we are. They do not want to disclose the nature of their products to their customers. We will need to coordinate the submission of all these documents to FDA so that we may obtain a timely response.

Please note, in the letter from the Witco Governmental Regulations Manager, he referred to the product as Emcol 4151. The correct name is Witcolate 4151.

Thank you for your help. If I can be of any assistance, please call.

DJP:avk
cc: Ashok Shah
Walt Edwards
Joel Simmons
Ralph Purtell
Al Matyger
Access File # 9283

Dave Poledna

Witco

Organics Division

Witco Corporation, 3200 Brookfield Street, Houston, Texas 77045 Telephone 713-433-7281

April 23, 1990

Mr. David Poledna
B. F. Goodrich
P. O. Box 122
Avon Lakes, OH 44012

Subject: Witco's product, Emcol 4151

Dear Mr. Poledna:

I am responding to your request for the FDA status of Witco's product, Emcol 4151.

Witco's product, ~~Emcol~~ Witcolate 4151, meets the requirements of Title 21 CFR 177.2600.

If you have any questions, please contact me.

Sincerely,

WITCO CORPORATION

Charles R. Green
Divisional Manager
Governmental Regulations

CRG:olb

10/26/92
Per [illegible] (Green's [illegible]) sodium alkyl phenol ether sulfate (Cas. No. 9014-90-8) at least 8% + in 177.[illegible]

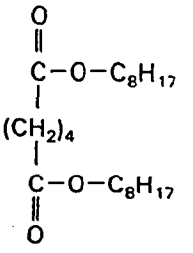
21797003

BFG16549

DOA

Monsanto

Dioctyl Adipate Di(2-Ethylhexyl) Adipate



General Description

DOA is a high quality plasticizer for imparting low-temperature flexibility to polyvinyl chloride and synthetic rubber compositions.

In polyvinyl chloride and synthetic rubber, DOA imparts a degree of softness, hand, and good heat and light stability. It offers good processing performance despite being a low-temperature plasticizer. DOA is a recommended plasticizer for films requiring good low temperature properties such as those used for food wrap.

In vinyl dispersions, DOA makes formulations that have good flow properties because of low initial viscosity. The viscosity does not build up greatly during storage, nor do the dispersions significantly increase in viscosity on exposure to high speed mixing (dilatency) or rapid spreading equipment. The high yield value of DOA aids in making no-sag spray coatings or no-drip plastisol dip coatings.

DOA is compatible and contributes a valuable plasticizing effect to nitrocellulose, ethyl cellulose, vinyl copolymers, and chlorinated rubbers. It is also useful in plastizing polyvinyl butyral, cellulose acetate-butyrate, polystyrene, and dammar wax.

In applications where the general performance provided by DOA is sought, even better low temperature flexibility and lower volatility performance can be obtained with the companion adipate ester, Santicizer® 97 plasticizer.

Toxicity & Handling

Based upon toxicity studies, DOA has a low order of toxicity and does not require special handling. Handle in accordance with good industrial hygiene and safety practices. These practices include avoiding unnecessary exposure and removal of the material from eyes, skin and clothing. Complete toxicity and handling information can be found on the Material Safety Data Sheet which is available upon request.

DOA complies with Food and Drug Administration regulations for use in food packaging materials in Sections 175.105, 175.300, 177.1200, 177.1210, 177.2600, and 178.3740 of the 21 Code of Federal Regulations. It also complies with U.S. Department of Agriculture regulations for use as an acceptable component of packaging materials in contact with meat or poultry food products prepared under Federal inspection.

Properties

Molecular Weight	371
• Acidity (meq/100 gm. max)	0.25
• Appearance	Clear, oily liquid
• Color (APHA) [max.]	25
• Moisture (KF in Methanol) %, max.	0.10
• Odor	Mild
• Refractive Index (@25°C)	1.444–1.448
• Specific Gravity (25°/25°C)	0.921–0.927
Density (@ 25°C) ca. lbs./gal.	7.72
Crystallizing Point (°C)	<–70
Pour Point (°C)	–65
Boiling Point @ 10mm Hg, °C	224
Vapor Pressure (mm Hg)	
@ 200°C	2.3
@ 250°C	32
Viscosity (Centistokes)	
@ 37.8°C	8.2
@ 98.9°C	2.4
Surface Tension @ 20°C (dynes/cm)	29
Thermal Expansion Coefficient @10°–40°C (cc/cc°C)	0.00078
Flash Point (C.O.C.) [°F.]	377
Fire Point (C.O.C.) [°F.]	450
Solubility In Water @ 25°C, %	<0.01
CAS Number	103-23-1

• Specification

*Registered Trademark of Monsanto Company

BFG16550

21797004

MEMORANDUM

TO: E. Antonucci

DATE: July 24, 1991

FROM: Vivienne Gaudette

CC: J. Baron
T. Brennan
R. Stangs, A. Romano
Chron

SUBJECT: DREWPLUS L-140 - FDA

Ed,

As requested by G. Tirpak on 7/17/91 (attachment 1) the subject product was reviewed (R. Stangs) for FDA acceptability (177.2600) - rubber articles intended for repeated use, and found to be acceptable. However, referring to T. Brennan's attached memo, (attachment 2) I noticed that the customer has concluded that 177.2600 includes use in flexible medical gloves. I do not see any reference to this application in the regulations. (attachment 3).

Regards,

Vivienne

VG:nvd

attachment