

4N 8313
10/1/92

November 20, 1992

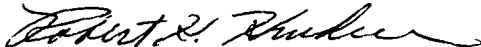
Joel M. Mirsberger, C.P.M.
Oscar Mayer
Foods Corp.
P.O. Box 7188
910 Mayer Ave.
Madison, Wi. 53707

Dear Mr. Mirsberger:

This letter is in response to your request for information on the FDA status of the recipe for PVC 411 which you supplied. Based on the description that you provided, the lubricant, Loxamid EBS, appears to be the limiting ingredient. The information that we have on this material indicates that 21CFR175.105 (Adhesives), 21CFR175.300 (Resinous and Polymeric Coatings), and 21CFR177.1210 (Closures and sealing gaskets for food containers) are the only sections for which this ingredient has clearance which are applicable to PVC.

Please refer to the above sections for verification. You can call me at (216) 447-7978 or Connie Dillon at (216) 447-7831 if you have any questions.

Sincerely,



Robert K. Hinderer, Ph.D.
Director, Health, Toxicology and Product Safety

21604001

BFG15689

Openmayer's PVC 411

Chemical
PVC Resin

TOA Slater
PS

DHP(83%) / DINA(17%)

178.3740 (24% Limit)
[175.300] 176.170 [177.120]
177.2600; [175.105]

atocem
912708552 Thermobite 813
Diethyl Tin Malate (100%)
Co. No. 16091-18-2

✓ 178.2650 (attraction limitation)

710138 Loxiol HOB7107
Pentaerythritol adipate Stearate

178.3690; 178.3280
(0.4%) (4%)

711619 Loxamid EBS
N, N'-ethylene bisstearamide
N,N'-ethylene bisstearamide

[175.105] [175.300]
177.1200; [177.1210]
(3) (2)
177.1350; 177.2470;
(6) (2)
177.2480

Limited Ford application

Limited to: 175.105 adhesives / Components of Coatings
175.300 Resins & polymeric coatings
177.1210 Closure w/sealing gaskets for
ford Containers

10/15 Coatings call
w/Bruce Jack
mitchell (open Aug 94)
a mitchell

21604002

BFG15690

October 19, 1992

Bruce Dovey

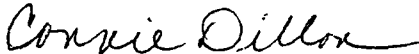
SUBJECT: FDA STATUS OF OSCAR MAYER'S PVC 411 COMPOUND

This will confirm our discussion regarding the status of PVC 411 under FDA's Indirect Food Additive regulations.

We have reviewed the recipe for PVC 411. The use of PVC 411 as an indirect food additive is limited to the following uses under CFR 21:

1. 175.105 - Substances for use only as components of adhesives.
2. 175.300 - Resinous and polymeric coatings.
3. 177.1210 - Closures w/sealing gaskets for food containers.

Furthermore, this compound must meet the extraction requirements as described under 21CFR 178.2650(b)(1).


Connie Dillon

1019-1/jp

cc: R. K. Hinderer

21604003

BFG15691

EKEK

AN 8312
J. 11.11.11

November 20, 1992

Joel M. Mirsberger, C.P.M.
Oscar Mayer
Foods Corp.
P.O. Box 7188
910 Mayer Ave.
Madison, Wi. 53707

Dear Mr. Mirsberger:

This letter is in response to your request for information on the FDA status of Geon 86223 TRANS PLTS 411 and Geon 86224 TRANS PLTS 413. Based on our evaluation of the recipes, the FDA clearance for these compounds is limited to 21CFR176.120 (use as an adjuvant in the manufacture of paper and paperboard products).

Please call me at (216) 447-7978 or Connie Dillon at (216) 447-7831 if you have any questions.

Sincerely,



Robert K. Hinderer, Ph.D.
Director, Health, Toxicology and Product Safety

21605001

BFG15692

001871 SF GOODRICH COMPANY MESSAGE SERVICE 13:03:43
FROM: R103R360 TO: CLEVMAIN DOCUMENT: 170004 152 LINES 11/17/92

ROUTE TO: DILLON, CONNIE N

GEON VINYL TECHNICAL DOCUMENT

R103360 G E O N V I N Y L RECIPE 11/17/92 13:03:39

GEON 86223 TRANS PLTS 411 LOC: 10 DEPT: 5796 ISSUE: 292
COMMODITY NO.: 86223 000 4118 EFFECTIVE DATE: 01/01/92
SBC NBR: 1311 DELETE FLAG: NO
LAB REF: CMFR:
BASED ON:
APPLICATION:

PARTS	INGREDIENTS	SEQ	LOC	PERCENT
63.15396	961 000498 110 X 450 FG	110	10	62.208
37.89237	931 710587 JAYFLEX 260 AD: 3066	210		37.325
1.15788	812 708552 THERMOLITE 813	310		1.158
1.31577	943 00L008 STEARONE	410		1.316
101.52000	Diheptadecyl Stearate 18-pentatriacontane	TOTAL		100.000

176.120(b); 177.1200
177.1400 b(4)

SPECIFIC GRAVITY: 1.21 HARDNESS: A-80
TYPE SAMPLE: COLOR: 2
ISSUED:
MARKETING APPROVAL:

*** FOOD GRADE CLEANUP REQUIRED ***

498: PVC Recip (9002 56-2)

FDA Clearance
PS

Jim Quince
713/870-6281
710887: *Cos. No. 84-75-3 28553-12-0
Plasticizer Proprietary

175.300; 176.170; 177.1210
177.2600; 178.3740
(2.30%)

708552: Di-n-Octylen Maleate
Thermolite 813 (Cos. No. 16091-18-2)
4-8: 18-pentatriacontane
(Cos. No. 504-53-0)

178.2650(2)
177.1850; 177.1910
176.120; 177.1200
177.1400 b(4)
Pg 243

*84-75-3 711100
Di-n-Octylen Maleate (63%)
(Plasticizer Grade, Di-n-Octylen Maleate)

Di-n-Octylen Maleate
Di-n-Octylen Maleate

21605002

BFG15693

REPORT: .BF GOODRICH COMPANY MESSAGE SERVICE 13:04:06
FROM: R103R360 TO: CLEVMAIN DOCUMENT: 170005 151 LINES 11/17/92

ROUTE TO: PILLON, CONNIE N

GEON VINYL RESTRICTED / TECHNICAL DOCUMENT

R103360 G E O N V I N Y L RECIPE 11/17/92 13:04:07

GEON 86224 TRANS PLTS 413 LOC: 10 DEPT: 5796 ISSUE: Y92
COMMODITY NO.: 86224 000 4138 EFFECTIVE DATE: 01/01/92
SBC NBR: 1311 DELETE FLAG: NO
LAB REF: CMFR:
BASED ON:
APPLICATION:

PARTS	INGREDIENTS	SEQ	LOC	PERCENT
59.54252	961 000498 110 X 450 FC	110	10	58.651
41.67976	931 710887 JAYFLEX 260	210		41.056
.14885	912 708552 THERMOLITE 813	310		.147
.14885	943 00L008 STEARONE	410		.147
101.51999		TOTAL		100.000

SPECIFIC GRAVITY: 1.20
TYPE SAMPLE:
ISSUED:
MARKETING APPROVAL:

HARDNESS: A-72
COLOR: 2

*Ingredients ok
as per 86223-411*

21605003

BFG15694

OSCAR MAYER FOODS CORPORATION



November 3, 1992

Mr. Bruce Dovey
BF Goodrich
6100 Oak Tree Boulevard
Cleveland, OH 44131

Dear Bruce:

A regulation became effective July 17, 1984 stating that all plants under USDA inspection must obtain written guarantees from suppliers stating that each material used in packaging meat or poultry products in the plant complies with federal food laws and regulations. The guarantee will be accepted by USDA inspectors to establish that the material can be legally used for packaging meat and poultry products.

Responsibility for providing guarantees to meat and poultry plants rests with the firm whose trade or firm name appears on the material as it is marketed to the plant. Meat and poultry plants must maintain a file containing guarantees for all packaging materials in the plant. This file must be open to USDA officials at all times. All packaging materials in the plant must be traceable to a guarantee in the file. USDA inspectors, however, retain the authority to refuse a specific material which they determine may cause adulteration of products.

The guarantee must state that all packaging materials and components of such which are intended to come in direct contact with a meat or poultry product comply with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations. Additionally, the guarantee must show:

1. Brand name or code designation of supply and components.
2. Name of Supplier
3. Specific conditions for use of material including temperature. If there are no conditions for use, please indicate same.
4. Signature and title of corporate official of supplier.
5. Guarantee should be continuing to cover all shipments, however a new guarantee must be supplied upon change in supply.

Further, it is requested that one(1) supply item be declared per form. Components for a supply are to be incorporated.

Accordingly, I am requesting that you provide a separate letter of guarantee in the attached format covering each item that you sell to any Oscar Mayer Foods Corporation location. Please send a copy of your letter directly to each of those plants' Purchasing Manager and one copy to me. It is essential that you cover all packaging materials sold to Oscar Mayer Foods Corporation or its subsidiaries.

Sincerely,

J. M. Mirsberger
J. M. Mirsberger
Senior Purchasing Agent

Attachment

PUR#1-24.WP



OSCAR MAYER FOODS CORPORATION, A KRAFFT GENERAL FOODS, INC. SUBSIDIARY
P.O. BOX 7188, MADISON, WISCONSIN 53707 TELEPHONE: 608-241-1111, TELEX: 26-5468

BFG15695

21605004



JOEL M. MIRSBERGER, C.P.M.
SENIOR PURCHASING AGENT

OSCAR MAYER
FOODS CORPORATION

P.O. BOX 7188
910 MAYER AVENUE
MADISON, WI 53707
(608) 241-6732
FAX (608) 241-6734

BFG15696

21605004 A

86223 TRANS PLTS 411

498: PVC Resin

710887: DHA(63%) DENA(37%)

708552: Di-n-Octyllin Maleate

4-8: Dikeptadecyl Ketone

86224 TRANS PLTS 413
FDA Clearance

Prior to 1980

175.105

175.300

176.170(c)

177.1210(b)

177.2600(<30%)

✓ 178.3740 (DENA < 24%) ^{1/3 4 3/3}

✓ 178.2650(a)(2)

177.1950 ~ 177.1980

[176.120(b) (<0.4%)]

[177.1200(c) (<0.35%)]

177.1400(b)(4) (0.35%)

not a PVC application

21605005

BFG15697