

AN-8686

FACSIMILE

November 5, 1993

TO: Cindy Johnson
Oscar Mayer
Fax No. 608/242-6159

SUBJECT: General FDA Status Assessment for XIIII 230 0801

A review of the present recipe indicates that this compound meets the current requirements of the FDA for use in contact with fatty, non-fatty, non-alcoholic foods, and under conditions of use F and G described in Table 2, 21CFR176.170(c) in accordance with 21CFR175.105 (Adhesives) 21CFR175.300 (Resinous and polymeric coatings), 21CFR176.170 (Components of paper and paperboard in contact with aqueous and fatty foods), 21CFR176.180 (Components of paper and paperboard in contact with dry foods), and 21CFR177.1210 (Closures with sealing gasket for food containers), and in contact with food of types I, II, IV-B (except liquid milk), VI-B (except carbonated non-alcoholic beverages), and VIII as described in Table 1 21CFR176.170(c).

Fat and Oil content of the food shall not exceed 30% by weight, and the final thickness in the form which they contact food shall not exceed 0.005 inches.

BFGoodrich Company


Connie N. Dillon
Regulatory and Data
Systems Specialist

bcc: Bob Kostur, (Fax: 708/232-6902)
Bob Schilling, (ALTC)

BFG16305

21729001

11-3-93

Bob Koster

Cyber

Gaby Johnson

re: Oscar Mayer

smaller
company

X-1111230-0801 newest ~~with~~ compound

changed from using Stearns

different plastic

Send some ^{type} letter as in June 29th

608/242-6159

met-Wrap application

cc: Bob Koster

fax 708/232-6922

BFG16306

21729002

C103D326 BFGOODRICH GEON VINYL DIVISION USERID: N50CND1A
 C103F326 GEON PROD RECIPE INQUIRY PTERMID: PV120093
 PRODUCT NBR: X1111 230 0801 X11112300801 PL LOC: 47 DEPT: 5617 ISSUE: 001
 SBC: 1311 EFFECTIVE DATE: 931005 INTERMEDIATE RM NBR:
 TOTAL LBS RM: 170.700000 LBS PRODUCT: 170.700000 RECIPE TYPE: 2

PAGE 1 OF 1

SEQ	RAW MATL	DESCRIPTION	QUANTITY	LC	PERCENT	COMMENTS
001	961-000538	110 X 450 FGAG	100.000000		58.5823	
002	931-711898	JAYFLEX 378	70.000000		41.0076	DINA (1%)
003	912-708552	THERMOLITE 813	0.250000		0.1465	
004	943-710138	LOXIOL HOB-7107	0.250000		0.1465	
005	943-00L035	EBS WAX POWDER	0.200000		0.1172	

711.898
 ALL AP-8094
 for clearance

DINA: 178.3740; 176.170e; 175.300; 177.1210e
 (3)

DHP: 175.105; 178.3740; 176.170e; 175.300; 177.1210e
 (3)

NEXT RESPONSE:
 DC900016 RECIPE INQUIRY OK

NEXT KEY:
 PF5-PROP PF6-RMKS PF9-SAFE PF10-INST

FDA Clearance
 Prior Sanction

538: PVC Resin
 711798: 1,2-Bis(hydroxyethyl)adipic acid, Diethylsterate
 Cas. No. 84-45-3; 28553-12-8
 707552: Di-n-Octylterephthalate
 Cas. No. 16091-18-2
 710138: Pentamethylol Adipate Sterate
 & Carth Oil
 4-35: N, N'-Ethylene bisstearamide
 175.105 (NR)
 175.300 (3)
 176.170e
 177.1210 (NR)
 178.3740
 DHP: (176.170e)
 DINA: 0.005 (1%)
 Table 2 (F&G)

175.105 (NR)
 DHP (NR)
 175.300 (3)
 NR
 176.170e
 Table 1, Type
 1, 11, IV-B, V, VIII
 Table 2 (F&G)
 177.1210 (NR)
 per 175.300 (3)
 178.3740
 DHP: (176.170e)
 DINA: 0.005 (1%)
 Table 2 (F&G)

4-35: 175.105 (NR)
 175.300 (NR)
 176.180 (NR)
 176.170e (type VIII)
 177.1210 (4)
 per 175.300 (3) NR

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DHP: (I) (II) ~~(III)~~ (VI-B) & VIII

non fatty or fatty foods

DINA: Non-Fatty, Fatty, ~~non-alcoholic~~ ^{& oil} fat Content
~~not exceeding~~ ^{less} than 30% by wt. Thickness .005 inches
USC conditions F & G Table 2

178.2650: Di-ethyl T in Malate: I, II, ~~III~~ (V-B (except liquid milk)),
V, ~~VI (except malt beverages)~~ ^{(except} Carbonated non-alcoholic beverages,
VII, (VIII) & IX

-- can with fatty and non fatty foods in --

I, II, IVB (except liquid milk), VIB (except carbonated
non alcoholic beverages), VIII in Table 1

20176.170 c under conditions F and G Table 2

Fat & oil content of the food shall not
exceed 30% by wt. and the final then --

21729004

BFG16308

need PVC alcohol footnote

Subject: X1111 230 0801 FDA Status Assessment

A review of the present recipe indicates that this Compound meets the current requirements of the FDA for use in accordance with 21 CFR 175.105 (additives), 21 CFR 176.180 (containers) and 21 CFR 177.1210 (injection), and in accordance with the use in contact with ~~food of type VII as described in Table 1 of 21 CFR 176.170 (C)~~ ^(except liquid milk) food of type I, II, IV-B, and VII as described in Table 1 of 21 CFR 176.170 (C). Use temperature per Table 2 of 21 CFR 176.170 (C) and the final thickness of the polymer in the form which they contact food shall not exceed 0.005 inches.

(over)

21729005

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