

AN 4629
deleted

October 30, 1989

P. J. Kruszynski
CL-OTM-3

SUBJECT: GEONS 87501 NAT 021, 87522 NAT 022 AND
87534-TR 001 - FDA STATUS

Geons 87501 Nat 021, 87522 Nat 022 and 87534 Tr 001 are composed of ingredients that meet the current requirements for use in contact with foods of type I, II, III, IV (except liquid milk), V, VI, VII, VIII and IX under use conditions D, E, F and G as described in Tables 1 and 2 of 176.170.

The ingredients in the above Geon compounds are either listed on an appropriate regulation in 21CFR parts 174 through 186, or are generally recognized as safe (GRAS), or prior sanctioned for such use. The final food contact article must meet the extractive limitations imposed by 21CFR 178.3790.

Although it may be suitable, clearance of a material for food contact applications does not necessarily confer acceptance for use in medical applications. In general, there are no regulations which prescribe the composition of medical devices or packaging. Each medical application is evaluated on an individual basis.

W. C. Bachtel

W. C. Bachtel

91030-2/jp

22137001

BFG19014

BFGoodrich

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DATE: October 30, 1989

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NUMBER OF PAGES 2 (INCLUDING COVER PAGE)

COMMENTS:

FROM: W. C. Bachtel PHONE: 216/374-3422

BFG19015

22137002

ROUTE TO: BATH COMPUTER ROOM

* GEON VINYL TECHNICAL DOCUMENT *

R103360

GEON VINYL RECIPE

10/30/89 09:23:15

Item 51301 MATERIAL 131
CORRUPTED FILE 0000000000000000
SEL NAME: 1311
LAB REF:
BASED ON:
APPLICATION:

OSHA WARNING LABEL: 4
LOCAL DEPT: 0007 ISSUE: 033
EXPIRATION DATE: 01/01/99
DELETE FLAG: NO
OSHA:

PART	INGREDIENTS	SEQ	LOC	PERCENT
63.04433	781 000023 100EP F-76	110	12	60.972
2.77133	791 710700 1001 A 30	210		2.727
4.15222	742 710200 BLENDEX 336	220		4.049
1.24366	712 710473 MARK 1334	310		1.213
8.30445	925 710356 ULTRAFFLEX H - <i>Ca. Carbometh</i>	410		8.097
1.66057	743 000034 CA STEARATE-FUSED	510		1.619
1.66059	743 000035 ETH BIS STEARAMIDE	520		1.619
102.36000		TOTAL		100.000

TYPE SAMPLE:
MATCHED TO:
ISSUED:
MARKETING APPROVAL:

**** FOOD GRADE CLEANUP REQUIRED ****

*metals lines - food types - 1- IX (except liquid milk
for conditions - D, E, F, & G*

extractions 178.3790

22137003

BFG19016

ROUTE TO: BATH COMPUTER ROOM

* GEON VINYL TECHNICAL DOCUMENT *

R103360

GEON VINYL RECIPE

10/30/89 09:29:01

GEON 87522 NATURAL 022

LOC 12 DEPT 5007

ISSUE 333

VISIBILITY NO: 87522 000 0220

EFFECTIVE DATE: 01/01/89

SEC NAME 1001

DELETE FLAG: NO

LAB REF:

CMFA

BASED ON:

APPLICATION:

PARTS	INGREDIENTS	SEC LOC	PERCENT
82.74379	961 000016 102EP F-S	110 12	80.873
4.77662	941 00K006 PARALOID K-120N	210	4.632
4.14719	942 710236 ELENDEX 333	220	4.044
.71238	912 710473 MARK 175+	310	.890
6.22078	925 709635 SUPER-PPLEX 200	410	6.066
1.11974	943 00L034 CA STEARATE-FUSED <i>calc</i>	510	1.092
1.99065	943 00L016 MINERAL OIL VSF	520	1.941
.24883	943 00L022 STEARIC ACID-FDA	530	.243
102.56000	TOTAL		100.000

TYPE SAMPLE:

MATCHED TO:

ISSUED:

MARKETING APPROVAL:

**** FOOD GRADE CLEANUP REQUIRED ****

methyl ter

BFG19017

22137004

ROUTE TO: BATH COMPUTER ROOM

* GEON VINYL TECHNICAL DOCUMENT *

R100000

G E O N V I N Y L R E C I P E

10/30/87 09:05:21

GEON VINYL TECHNICAL DOCUMENT
COMMUNITY NO.: 07004 000 0018
SEQ NO: 1001
LMD REF:
BASED ON:
APPLICATION:

GEON VINYL TECHNICAL DOCUMENT
LMD NO: 1001-1001
EFFECTIVE DATE: 01/01/87
DELETE FLAG: NO
LMDR:

PARTS	INGREDIENTS	SEQ	LOC	PERCENT
67.71366	961 000470 SOX1 PG	110	16	67.720
2.62140	741 707200 PARALOID XT12000	210		2.623
7.17707	942 710649 PARALOID B1A 733	220		7.034
1.79426	912 710473 MARK 1984	310		1.758
.00397	921 00B273 VIOLET 5012 (RS-12)	410		.009
.02691	961 000111 85367 000 4302	420		.026
.44636	943 00L021 STEARIC ACID USF GR	510		.440
.13437	943 00L027 POLYETHYLENE AC629A	520		.132
.04485	943 00L040 ARISTOWAX 165 FWD	530		.044
102.04000	<i>Proffman - 1001/105</i> TOTAL			100.000

TYPE SAMPLE:
MATCHED TO:
ISSUED:
MARKETING APPROVAL:

COLOR: 2

**** FOOD GRADE CLEANUP REQUIRED ****

85367-000-4302

1101377-92.0

8PM Sargbeoil 3.0
UltraMarineBlue 2.0

Methyl Tan

BFG19018

22137005