

March 18, 1993

To: Mark Hross

SUBJECT: GEON RAW MATERIAL FDA STATUS

This is in response to your request for assistance in determining what FDA indirect food additive clearances exist for selected Geon raw materials. The purpose of this letter is to explain the process, to provide issues that need to be considered, and to provide recommendations relevant to this specific task and future needs.

Before we get into the meat of this subject, it is important to note that FDA goes to lengths to emphasize that they do not "approve" any product. The proper terms to use are "clearance", or, "acceptability".

Determination of the acceptability and raw materials for indirect food additive applications is the prime responsibility of the manufacturer. Only the manufacturer has the information necessary to determine whether its product (chemistry, purity, and process) meets the requirements of the various indirect food additive sections.

Once the supplier provides a list of the specific clearances for their raw material (i.e., 21CFR175.105, 21CFR177.2600, etc.), we verify the chemical's listing and note specific limitations prior to determining what clearances the Geon compound has.

~~Frequently, issues arise which require further information from the supplier, or resolution via external opinions.~~

In the past, Chuck Purks was the person responsible for contacting suppliers and obtaining information on the FDA clearances for their products. While this is something that we could do, it is probably not the best way to manage the process particularly in light of Geon's decision to assume full responsibility for its FDA activities in 1994. Furthermore, we cannot assume this task and still handle the daily FDA, USDA, and NSF activities, as well as the FDA audit.

In order for Geon to be prepared to insure compliance and provide timely responses to customer needs, it is essential that Geon obtain the staff necessary to meet these needs.


Bob Hinderer

0318-1/jp

cc: L. Maresca
D. Marshall
M. Marshall

C. Mattia
K. Willings

21762001

BFG16456

INTEROFFICE MEMORANDUM

To: R. Hinderer - OTM-3
cc: D. Marshall - OTM-2

Date: March 18, 1993
From: M. Hross
Dept: Unknown
Phone: x7601
Loc: OTM-3

RECEIVED
MAR 18 1993
R. HINDERER

Subject: FDA Approvals and Restrictions for Select Geon® Raw Materials

Under our contract agreement for FDA support, please find attached a list of sixteen Geon® raw materials which have conflicting FDA approval statements from our suppliers. That is, these raw materials have multiple suppliers with conflicting FDA information supplied by each.

At your earliest convenience please supply FDA approvals and restrictions (listing appropriate references) for use of each of the attached raw materials. *Please note* that the raw material chemistries are also attached.

Your supplied information will then be used to resolve the conflicts in our database.

21762002

BFG16457

C617D096
C617F096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: NSOMSH1A
PTERMID: PV120028

INVENTORY NUMBER : 925 / 00 / 1005

CAS NO.	CONCT PCT.	DESCRIPTION
1317-65-3	100.0000	LIMESTONE

NEXT RESPONSE: RMCASING NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED
SB LT-1 Aa

04/043

21762003

BFG16458

C6170096
C617F096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: NSOMSHIA
PTERMID: PV120028

INVENTORY NUMBER : 929 / 00 / 1026

CAS NO.	CONCT PCT.	DESCRIPTION
7439-92-1	000.0001	LEAD
7439-97-6	000.0001	MERCURY
7440-43-9	000.0001	CADMIUM
7631-89-9	100.0000	SILICON DIOXIDE

NEXT RESPONSE: RMCASINQ NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED

SB LT-1 Aa

04/043

BFG16459

21762004

C817D096
C617F096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: N50MSH1A
PTERMID: PV120028

INVENTORY NUMBER : 931 / 00 / P075

CAS NO.	CONCT PCT.	DESCRIPTION
117-81-7	100.0000	1,2-BENZENEDICARBOXYLIC ACID, [BIS(2-ETHYLHEXYL)]

NEXT RESPONSE: RMCASINQ NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED
SB LT-1 Aa

04/043

21762005

BFG16460

21762006

BFG16461

04/043

684LT-1
NO MORE CAS NUMBERS TO BE DISPLAYED
NEXT RESPONSE: RMCASINO
NEXT KEY:

6817D096
6817F096
CAS NO: 68149-79-1
CONCT PCT: 100.0000
DESCRIPTION: POLYMERIC ESTER OF ADIPIC ACID
INVENTORY NUMBER: 932 / 00 / 001

INVENTORY NO / CAS INQUIRY
GEOM PROD
USERID: NSCMSHA
PTERMID: FV120028

C617D096
C617F096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: NS0MSH1A
PTERMID: PV120028

INVENTORY NUMBER : 934 / 00 / P047

CAS NO.	CORCT PCT.	DESCRIPTION
103-33-1	100.0000	HEXANEDIOIC ACID, BIS(2-ETHYLHEXYL) ESTER
7439-92-1	000.0001	LEAD

NEXT RESPONSE: RMCASINQ NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED

SB LT-1 Aa

04/043

21762007

BFG16462

C617D096
C617F096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: N50MSH1A
PTERMID: PV120028

INVENTORY NUMBER : 935 / 00 / P031

CAS NO.	CONCT PCT.	DESCRIPTION
CRC-CP-0	000.0099	CHROMIUM (HEXAVALENT) COMPOUND
7439-92-1	000.0099	LEAD
7439-97-6	000.0099	MERCURY
7440-43-9	000.0099	CADMIUM
8013-07-8	100.0000	EPOXIDIZED SOYBEAN OIL

NEXT RESPONSE: RMCASINQ NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED

SBOLT-1 Aa

04/043

21762008

BFG16463

06170096
0617F096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: NSOMSH1A
PTERMID: PV120028

INVENTORY NUMBER : 939 / 00 / P055

CAS NO.	CONCT PCT.	DESCRIPTION
80-05-7	000.5000	PHENOL, 4,4'-(1-METHYLETHYLIDENE)BIS-
117-81-7	000.1000	1,2-BENZENEDICARBOXYLIC ACID, {BIS(2-ETHYLHEXYL)}
3319-31-1	099.0000	TOTM PLASTICIZER

NEXT RESPONSE: RMCASINQ NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED

CB LT-1 Aa

04/043

21762009

BFG16464

C617D096
C617F096

INVENTORY NO. / CAS INQUIRY
GEON PROD

USERID: N50MCH1A
PTERMID: PV120028

INVENTORY NUMBER : 945 : 00 / 1003

CAS NO.	CONCT PCT.	DESCRIPTION
80-05-7	000.5000	PHENOL, 4,4'-(1,1-METHYLETHYLENE)BIS-
117-81-7	000.1000	1,2-BENZENEDICARBOXYLIC ACID, {BIS(2-ETHYLHEXYL)}
3319-31-1	099.0000	TOTM PLASTICIZER

NEXT RESPONSE: RMCASING NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED
SB~~LT~~-1 Aa

04/059

21762010

BFG16465

0617D096
0617F096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: NS0MSH1A
PTERMID: PV120028

INVENTORY NUMBER : 943 / 00 / 1016

CAS NO.	CONCT PCT.	DESCRIPTION
80-05-7	000.0000	PHENOL, 4,4'-(1-METHYLETHYL OXENE)BIS-
117-81-7	000.1000	1,2-BENZENEDICARBOXYLIC ACID, (BIS(2-ETHYLHEXYL))
3319-31-1	099.0000	TOTM PLASTICIZER

NEXT RESPONSE: RMCASING NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED
SB LT-1 Aa

04/059

21762011

BFG16466

06170096
0617E096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: NSOMSH1A
PTERMID: PV120028

INVENTORY NUMBER : 943 / 00 / L035

CAS NO	CONCT PCT.	DESCRIPTION
57-11-4	002.0000	OCTADECANOIC ACID
110-30-5	098.0000	N,N'-ETHYLENEBISSTEARAMIDE

NEXT RESPONSE: RMCASINQ NEXT KEY:

NO MORE CAS NUMBERS TO BE DISPLAYED

SB LT-1

Aa

04/043

BFG16467

21762012

0617D096
0617F096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: NSOMSH1A
PTERMID: PV120028

INVENTORY NUMBER : 919 / 00 / S048

CAS NO.	CONCT PCT.	DESCRIPTION
000-00-0	000.0099	CHROMIUM (HEXAVALENT) COMPOUNDS
151-57-7	100.0000	2-HYDROXY-4-METHOXYBENZOPHENONE
7439-92-1	000.0099	LEAD
7439-97-6	000.0099	MERCURY
7440-43-9	000.0099	CADMIUM

NEXT RESPONSE: RMOASING NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED

SB LT-1 Aa

04/043

21762013

BFG16468

0617D096
0617F096

INVENTORY NO / CAS INQUIRY
GEN PROD

USERID: N50MSH1A
PTERMID: PV120026

INVENTORY NUMBER : 953 / 60 / 6013

CAS NO.	CONCT PCT.	DESCRIPTION
105-74-8	098-0000	PEROXIDE, BIS(1-OXODODECYL)

NEXT RESPONSE: RMCASINQ NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED

SB#LT-1

Aa

04/043

21762014

BFG16469

06170096
06177096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: M5OMSH1A
PTERMID: PV120028

INVENTORY NUMBER : 953 / 00 / 6115

CAS NO.	CONCT PNT.	DESCRIPTION
79-10-7	079.7000	2-PROPENOIC ACID

NEXT RESPONSE: RMCASING NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED

SB L f-1 Aa

04/043

21762015

BFG16470

06170096
06170096

INVENTORY NO 7 CAS INQUIRY
GEON PROD

USERID: NSOMSHIA
PTERMID: PV120028

INVENTORY NUMBER : 955 / 00 / M008

CAS NO.	CONCT PCT.	DESCRIPTION
140-88-5	100 0000	2-PROPENOIC ACID, ETHYL ESTER

NEXT RESPONSE: RMCASING NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED
SB LT-1 Aa

04/045

21762016

BFG16471

06170096
00170096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: NSOMSH1A
PTERMID: PV120028

INVENTORY NUMBER : 957 / 00 / W018

CAS NO.	CONCT PCT.	DESCRIPTION
000-00-0	000.0009	CHROMIUM (HEXAVALENT) COMPOUNDS
131-21-3	030.0000	SULFURIC ACID MONODODECYL ESTER SODIUM SALT
7439-92-1	000.0099	LEAD
7439-97-6	000.0009	MERCURY
7440-43-9	000.0009	CADMIUM
7732-18-5	070.0000	WATER

NEXT RESPONSE: RMCASINQ NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED

SB LT-1 Aa

04/043

21762017

BFG16472

C6170096
C617F096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: NSOMSHIA
PTERMID: PV120028

INVENTORY NUMBER : 957 / 00 / W056

CAS NO.	CONCT PCT.	DESCRIPTION
CRC-CP-D	000.0009	CHROMIUM (HEXAVALENT) COMPOUNDS
7439-92-1	000.0009	LEAD
7439-97-6	000.0009	MERCURY
7440-43-9	000.0009	CADMIUM
7732-18-5	060.0000	WATER
68439-57-6	040.0000	AOS

NEXT RESPONSE: RMCASINQ NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED

SB LT-1 Aa

04/043

21762018

BFG16473