

Toxicologic Report

00793

AN = 1745
dated

TO: The B. F. Goodrich Company
Att. Mr. W. E. McCormick

May 7, 1970

SUBJECT: Sample Geon 83403

The above material was subjected to Type A Tests I, II and III. The following data were obtained:

1. There was no significant acute toxicity with the eluates.
2. Intracutaneously, there was a mild reaction at 24 hours; reduced to slight at 48 hours; with a trace reaction remaining at 72 hours with the PEG eluate: no reaction with the other eluates.
3. Sections implanted intramuscularly for 72 hours remained free of significant tissue reaction.
4. It was nonpyrogenic.

Respectfully submitted,

Report to J. H. Kiefer

Dwight P. Blankenbaker
Dwight P. Blankenbaker, M.S.
Toxicologist

kw

BFG08482

20979001

Sample Geon 83403

May 7, 1970

The following preparations were made:

- 10 gms Geon material - covered with 50 ml 0.9% saline
- 10 gms Geon material - covered with 50 ml 5% ethyl alcohol in saline
- 10 gms Geon material - covered with 50 ml cottonseed oil (CSO)
- 10 gms Geon material - covered with 50 ml polyethylene glycol (PEG)

All preparations were warmed to 70°C for 24 hours along with 50 ml control portions of each menstruum, shaken, and the supernate poured off for testing.

The eluates were clear.

IA Acute Toxicity

<u>Menstruum</u>	<u>Dose</u>	<u>Route</u>	<u>No. Mice</u>	<u>Deaths to 72 hours</u>
Saline 0.9% eluate	1.0 ml	I.V.*	15	0
" control	1.0 ml	I.V.	5	0
5% ethyl alcohol eluate	1.0 ml	I.V.	15	0
" " " control	1.0 ml	I.V.	5	0
CSO eluate	1.0 ml	I.P.**	15	0
" control	1.0 ml	I.P.	5	0
PEG eluate	8,000 mg/kg	I.P.	10	0
" "	10,000 mg/kg	I.P.	10	0
PEG control	8,000 mg/kg	I.P.	10	0
" "	10,000 mg/kg	I.P.	10	0

* = intravenously ** = intraperitoneally

The saline, 5% ethyl alcohol in saline and cottonseed oil eluates were injected undiluted. The polyethylene glycol 400 eluate and control was diluted as follows:

2.8 ml + 7.2 ml saline (8,000 mg/kg)
 3.6 ml + 6.4 ml saline (10,000 mg/kg)
 and 0.025 ml injected per gm of mouse, i.e. 0.5 ml for a 20 gm mouse.

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B Intracutaneous Reactivity

The 0.9% saline, 5% ethyl alcohol in saline and cottonseed oil were injected undiluted 0.2 ml into each of ten blebs in each of two rabbits, paralleled by ten like control menstruum blebs. The polyethylene glycol 400, eluate and control, was diluted such that the 0.2 ml bleb injection volume contained 24 mgs and two rabbits received ten blebs of each.

Results:

0.9% saline eluate
and control: No significant reaction

5% ethyl alcohol in
saline and control: No significant reaction

CSO eluate and
control: No significant reaction

PEG eluate: There was a mild reaction
at 24 hours; reduced to
slight at 48 hours; with
a trace reaction remaining
at 72 hours.

PEG control: No significant reaction

II Intramuscular Tissue Reaction

Acute implants in rabbits

Rabbit 1 Implanted

Four Geon sections
Four USP controls

No gross reaction to 72 hours

Autopsy:

Geon sample: No significant tissue reaction

Control: No significant tissue reaction

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Rabbit 2 Implanted

Four Geon sections
Four USP controls

No gross reaction to 72 hours

Autopsy:

Geon sample:	No significant tissue reaction
Control:	No significant tissue reaction

III Pyrogenicity

A ten gram portion of the Geon material was prepared and covered with 200 ml of pyrogen-free saline and heated to not less than 85°C for one hour, cooled to 37°C and 10 ml of the eluate injected per kg of bodyweight. Body temperatures were recorded to three hours.

Results:

Total rise: 0.00°C. It was, therefore, nonpyrogenic.

BFG08485

PYROGEN TEST RECORD

Test No. BF422016

Substance Polyvinyl Chloride - Geon 83403

Source B. F. GOODRICH

Date 4-22-50

Room Temp. 22.8

Saline Control No. 542330

Animal No.	I	II	III	IV	V	Comments:
Weight (kg.)	4.2	2.9	3.8			☒ Standard Procedure: A <u>10</u> gram, _____ unit, portion of the test material was prepared, covered with <u>200</u> ml pyrogen-free saline, heated to not less than <u>85</u> °C for one hour, decanted, the eluate adjusted to 37°C and 10 ml injected intravenously per kg of body weight. ☐ Special Procedure:
Present	4.2	2.9	3.8			
Last Used	4-20	4-20	4-20			
Identification	145	148	148			
The Test: <u>4-22-50</u> Date						
Control Temperature °C	39.30	39.20	39.60			
Injection { Time Amount c.c.	10:30 42 ml	10:30 29 ml	10:30 38 ml			
Temperature Reading °C After Injection:						
1 hr.	39.30	39.20	37.80			
2 hr.	39.30	39.20	37.40			
3 hr.	39.30	39.20	39.40			
Rise Over Control	0.00	0.00	0.00			Total Rise °C: <u>0.00</u>

Substance is: ☒ Non Pyrogenic ☐ Pyrogenic

Tested by Richard R. Bennett
 Approved by Walter P. Blankenhorn

Huntingdon Research Center, Inc.

Box 6857.

Baltimore, Maryland 21204

REF. NO. 300-2

BFG08486

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H.R.C.**HUNTINGDON RESEARCH CENTER, INC.**(AREA CODE)
301

825-3484

BALTIMORE, MD. 21204
BOX 8887

Mr. W. E. McCormick, Manager
Department of Industrial Hygiene & Toxicology
The E. F. Goodrich Company
5600 N. Main Street
Akron, Ohio - 44318

DATE May 11th, 1970

FOR PROFESSIONAL SERVICES

Sample Geon 83403

AIB

\$122.00

AIB

60.00

AII

62.00

AII

26.50

\$270.50

Nº 4263

BFG08487

TO	W. C. Bachtel	FIELD POINT OR DEPT. & BLDG. NO.	Akron	DATE YOUR LETTER
FROM	C. H. Long	FIELD POINT OR DEPT. & BLDG. NO.	Cleveland D/5401	DATE THIS LETTER
SUBJECT				

Listed below are the formulations for Geon 8800 and Geon 8843 which were supplied by Nalge to the University of Pittsburgh. These are the formulations which I estimate were active during the time periods in question.

Geon 8843 Trans 001 (Issue 009)

Geon 92	100.0
P-51-Santicizer 409	45.0 - 6.230
P-31 Epoxy Soya	5.0
S-46-Mark WS - Ba. la soaps	1.5
S-47-Mark C - phosphate ester	0.5
8499-420 Master Batch - U-10	0.3
L-40-Sunolite 160 - Paraffin wax	0.2

Geon 8800 Trans 001 (Issue 002)

Geon 118 (Geon 92 predecessor) 100x308	100.0
P-34-Hercoflex 707 - Diphenyl ether	41.0
P-31-Epoxy Soya	5.0
S-47-Mark C - phosphate ester	0.5
S-46-Mark WS - Ba. la soaps	1.5
8599-420 Master Batch -	0.3
L-2-Stearic Acid -	0.2

Enclosed is a copy of the letter sent to Nalge from the University of Pittsburgh.

Please keep me advised of your correspondence on this matter. Thanks.

C. H. Long
C. H. Long

CHL/etm

Enclosure (1)

cc: D. Kent

D. G. Kuharik

G. A. Small

83405 -
83408 - N.T. - Nalge



University of Pittsburgh

SCHOOL OF MEDICINE
Department of Physiology

Phone 3/4/77

March 15, 1977

Mr. Joe Corbett
Nalge Company
Division of Sybron Corporation
16 Garden Street
Auburn, New York 13021

Dear Mr. Corbett:

I am writing to ask for information about possible changes in the composition of PVC grade SHH-FR which may have occurred between 1969 and 1976. We have been using Synthovar extruded cable, purchased from Varflex Corporation for chronic indwelling right heart catheters in rhesus monkeys. Whilst we recognize that the material is not of medical grade, but designed for electrical insulation, we had no problems with the first batch bought in 1969 but which we ran out of last year. More or less coinciding with the use of a new batch (bought October, 1976), we have had a number of sudden and relatively unexpected deaths in monkeys. I have recently become aware of the concern which has arisen from the use of PVC umbilical catheters in human newborn infants, especially regarding the leaching of plasticizers from the catheters (Hillman, S., Goodwin, S.L. and Sherman, W.R., New England Journal of Medicine 292:381-386, 1975). I would be grateful for any information you can give me about the use of plasticizers such as Di-(2-Ethylhexyl)phthalate in the SHH-FR plastic and whether the composition has changed between 1969 and 1976. We have noted that the first batch was distinctly yellow but the new material is quite colorless.

Finally, we would be grateful for information concerning catheter material of medical grade which you may make, which might be more suitable for chronic cardiac catheterization, together with any details on toxicological studies.

Yours sincerely,
P. E. Belchetz
P.E. Belchetz
412-624-2451

PEB/crs

① Contacted Dick Koopp
of B.F. Goodrich [tel-368-
[tel-368-9400]. B.F.G.
will contact Belchetz
re differences between
8800 & 8843 Compound
ingredients

Say Hello to
Dan Kent
et al.
L. Anne Belchetz

BFG08489

20979008

→ Call to Joe Corbett

called B/S 3-22-77 w/call Belch. responded 3/22/77

3300
used to

105°C

Super Hi Heat
Fungus Resistant
BF Goodrich
8843

type of
monomer
used in
medical
grade
catheters

1305