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Toxicologic Report

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

November 26, 1969

SUBJECT: Project R-90616
X-1053 Plastic Inflatable Catheters
Control

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 is nonpyrogenic.

Respectfully submitted,

David A Deboer
Toxicologist

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PROJECT R-90616

X-1053 Plastic Inflatable Catheters

Control

November 26, 1969

The following preparations were made:

10 gms X-1053 material -- covered with 50 ml 0.9% saline
10 gms X-1053 material -- covered with 50 ml 5% ethyl alcohol in saline
10 gms X-1053 material -- covered with 50 ml cottonseed oil (CSO)
10 gms X-1053 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.

The polyethylene glycol dilutions were mildly turbid.

I A Acute Toxicity

Menstruum	Dose	Route	No. Mice	Deaths to 72 hours
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 eluate 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; a trace reaction remaining at 72 hrs.
PEG control:	No significant tissue reaction

II Intramuscular Tissue Reaction

Acute implants in rabbits

Rabbit 1. Implanted:

Four X-1053 sections
Four USP controls

No gross reaction to 72 hours

Autopsy:

X-1053: No significant tissue reaction
Controls: No significant tissue reaction

Rabbit 2. Implanted:

Four X-1053 sections
Four USP controls

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Rabbit 2 (cont'd)

No gross reaction to 72 hours

Autopsy:

X-1053: No significant tissue reaction
Controls: No significant tissue reaction

III Pyrogenicity

A ten gram portion of the X-1053 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 body weight. Body temperatures were recorded to three hours.

Results:

Total rise: 0.10°C. It is, therefore, nonpyrogenic.

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PYROGEN TEST RECORD

Test No. BF1124940 Date 11-24-69

Substance PVC URINARY CATHETERS #X1053 Room Temp. 72° F

Source B. F. GOODRICH Saline Control No. 205

Animal No.	I	II	III	IV	V
Weight (kg.) Previous	2.8	3.9	3.0		
Weight (kg.) Present	2.9	3.9	3.0		
Last Used	11-20	11-20	11-20		
Identification	107	109	111		
The Test: Date 11-24-69					
Control Temperature °C	39.0	39.0	39.0		
Injection Time	2:00	2:00	2:00		
Injection Amount c.c.	29 ml	39 ml	30 ml		
Temperature Reading °C After Injection: 1 hr.	39.0	39.0	39.0		
2 hr.	39.0	39.0	39.2		
3 hr.	39.0	39.0	39.0		
Rise Over Control	0.00	0.00	0.10		

Comments:

☑ Standard Procedure:

A 10 gram, _____ unit, portion of the test material was prepared, covered with 200 ml pyrogen-free saline, heated to not less than 75 °C for one hour, decanted, the eluate adjusted to 37°C and 10 ml injected intravenously per kg of body weight.

☐ Special Procedure:

Total Rise °C: 0.10

Substance is: Non Pyrogenic ☑ Pyrogenic ☐

Tested by Jo Anne S. Bittner

Approved by David A. Behm

Huntingdon Research Center, Inc. Box 6857, Baltimore, Maryland 21204

REF. NO. 300-2

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Toxicologic Report

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

November 26, 1969

SUBJECT: Project R-90616
X-1054 Plastic Inflatable Catheters
Discolored

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 is nonpyrogenic.

Respectfully submitted,

Toxicologist

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PROJECT R-90616

X-1054 Plastic Inflatable Catheters

Discolored

November 26, 1969

The following preparations were made:

10 gms X-1054 material -- covered with 50 ml 0.9% saline
10 gms X-1054 material -- covered with 50 ml 5% ethyl alcohol in saline
10 gms X-1054 material -- covered with 50 ml cottonseed oil (CSO)
10 gms X-1054 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.

The polyethylene glycol dilutions were mildly turbid.

I A Acute Toxicity

Menstruum	Dose	Route	No. Mice	Deaths to 72 hours
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	1
PEG control	8,000 mg/kg	I.P.	10	0
" "	10,000 mg/kg	I.P.	10	1

* 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 eluate 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; a trace reaction remaining at 72 hrs.
PEG control:	No significant tissue reaction

II Intramuscular Tissue Reaction

Acute implants in rabbits

Rabbit 1. Implanted:

Four X-1054 sections
Four USP controls

No gross reaction to 72 hours

Autopsy:

X-1054: No significant tissue reaction
Controls: No significant tissue reaction

Rabbit 2. Implanted:

Four X-1054 sections
Four USP controls

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Rabbit 2 (cont'd)

No gross reaction to 72 hours

Autopsy:

X-1054: No significant tissue reaction
Controls: No significant tissue reaction

III Pyrogenicity

A ten gram portion of the X-1054 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 body weight. Body temperatures were recorded to three hours.

Results:

Total rise: 0.20°C. It is, therefore, nonpyrogenic.

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PYROGEN TEST RECORD

Test No. BF1124941 Date 11-24-69

Substance PVC URINARY CATHETERS #X1054 Room Temp. 72° F

Source B. F. GOODRICH Saline Control No. 205

Animal No.	I	II	III	IV	V
Weight (kg.) Previous	2.4	3.0	2.3		
Weight (kg.) Present	2.4	3.0	2.3		
Last Used	11-20	11-20	11-20		
Identification	144	146	148		
The Test: 11-24-69 Date					
Control Temperature °C	39.0	39.8	39.7		
Injection Time	2:00	2:00	2:00		
Injection Amount c.c.	24 ml	30 ml	23 ml		
Temperature Reading °C After Injection: 1 hr.	39.5	39.8	39.5		
2 hr.	39.3	39.7	39.6		
3 hr.	39.4	39.6	39.7		
Rise Over Control	0.20	0.00	0.00		

Comments:

☑ Standard Procedure:

A 10 gram, _____ unit, portion of the test material was prepared, covered with 200 ml pyrogen-free saline, heated to not less than 25 °C for one hour, decanted, the eluate adjusted to 37°C and 10 ml injected intravenously per kg of body weight.

☐ Special Procedure:

Total Rise °C: 0.20

Substance is: Non Pyrogenic ☑ Pyrogenic ☐

Tested by Deanna L. Bostock

Approved by David A. Johnson

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Huntingdon Research Center, Inc. Box 6857, Baltimore, Maryland 21204

REF. NO. 300-2