

BFG TECHNICAL DOCUMENT

B.F. GOODRICH CHEMICAL COMPANY TECHNICAL REPORT

SEP 30 1975

AN-2194
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TITLE Sunlite Plastics, Inc. Tubing Extractions		
AUTHOR H. H. Marty (HHM-16-75)	LOCATION Avon Lake Technical Center	DATE 9/16/75
REQUESTED BY: G. F. Cohan	LOCATION Cleveland Office	PROJECT NO.

Introduction

Sunlite made tubing for intravenous feeding from Geon® G-92 resin during 1974 and 1975. On 7-14-75, the first complaint occurred based on an extraction test Sunlite employed. A floccy material was found in tubing with a 5% sodium bicarbonate solution and with a 5% dextrose + 0.2% sodium chloride solution. American Hospital analyzed the floc and stated it was glycol monostearate.

BFG then substituted 11OX402 (103EP UPS-1) for the G-92 to determine if this were more acceptable. On 8-28-75, Sunlite said they obtained a floc when a tube was filled with water and held for 24 hours.

Our Analytical Group looked at the flocs from the three pieces of tubing. The precipitate on the wall of a bottle made by A. T. Kukic was also analyzed.

Summary

1. The floc extracted from the tubing made from G-92 was sorbitan monostearate. This is Span 60 or Glycomol S. Both the Infra-red and the Mass Spectrometer verify the analysis. No other material was present.
2. The floc extracted from the tubing made from 11OX402 was a cellulosic. This cellulosic does not correspond to MOC F-50, PVA or Tween 21 which are present in 11OX402. The 11OX402 made at Louisville was extracted separately and showed the presence of MOC F-50, PVA and Tween 21.
3. The bottle made from G-92 (compound 83408) had contained tap water for over one year. The analysis of the precipitate on the wall did not uncover any composition which helped to solve the Sunlite problem.

Recommendations

1. Do not supply G-92 resin for an application where the Span 60 can be extracted by water or a water solution.

September 16, 1975

Acknowledgements

The Analytical Group of Staff Technical Services did a fine job in determining the compositions of the samples. Those who worked on the problem were J. L. Dorsch (Mass Spec), M. M. O'Mara, J. W. Ryan (Infra-red) and R. A. Yount (Atomic Absorption).

Discussion

The toxicity of sorbitan monostearate in the blood stream is not positively determined. However, the high quantity of floc that was extracted from the tubing in a simulated intravenous procedure leads us to recommend that G-92 not be used for this application. For one, the floc is so heavy it might plug the needle. But, the telling blow is the aesthetic appearance of the floc in the tubing. That quality wouldn't sell.

Jack Ryan looked at the floc from the tubing made with 110X402. He ran the spectra for MOC F-50 which we use in the recipe. He extracted the 110X402 resin made at Louisville (done at room temperature for 24 hours using DM water). In the extract, he found MOC F-50 (the spectra was not charged from the charged material), Vinol 540, PVA and Tween 21. The floc from the tubing contained a cellulosic. It was not MOC F-50 and there was no PVA or Tween 21. Therefore, the data does not support the implied claim that the floc extracted from the tubing was one of our dispersants. The floc appears to be a contaminant--or else, the resin used was not 110X402. Jack will try to define the resin used. (See J. W. Ryan's attached report.)

A lot of work went into trying to identify the precipitate on the wall of the bottle made by Andy Kukic. The bottle was filled with tap water and held over a year. The inside wall was covered with a yellow film. The film was 10-15% ester and 85-90% salt of a fatty acid. The ester was Span 60. The fatty acid was a stearate of calcium. There was a small amount of iron and very low levels of phosphorous and zinc. Apparently the calcium in the water reacted with the stearate of the Span 80 during the year's contact. (See R. A. Yount's attached report.)

Future Work

1. You suggested getting tubing made at Louisville from 83403, 83405 or 83408. These could be extracted and the extract analyzed. This can be done.


H. H. Marry

HMM:pj

Reports Attached:

1. Examination of Sludge From Water Exposed to Tubing Made from 110X402 Resin, J. W. Ryan (JWR-64-75), 9-16-75.
2. White Precipitate from Inside Tubing Used for Medical Applications, R. A. Yount, 9/22/75.

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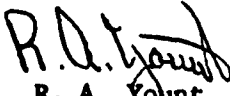
TITLE EXAMINATION OF SLUDGE FROM WATER EXPOSED TO TUBING MADE FROM GEON 110X402 RESIN		
AUTHOR J. W. Ryan JWR-64-75	LOCATION ALTC	DATE 9/16/75
REQUESTED BY: H. H. Marty	LOCATION ALTC	PROJECT NO. 3295
SUMMARY Sunlite Plastics makes tubing from our 110X402 resin. This is supplied to American Hospital Supply Co. for intravenous applications. Sunlite obtained a precipitate on the inside wall of the tubing during the course of extraction tests using distilled water. Because of the end use of this product we need to know the identity of the precipitate and how to prevent its occurrence. This material is essentially a cellulose derivative. The infrared spectrum indicates that it is not the methoxy cellulose MOC F-50 which we use. Several details of the spectrum differ from equivalent water extractions of our resin 110X402. We extracted our Louisville resin 24 hours with distilled water at room temperature. An infrared spectrum was recorded of the dried residue from this extraction after the careful evaporation of the water using a nitrogen stream and low heat. The spectrum showed MOC, a trace of polyvinyl alcohol (Vinol 540) and, Tween 21. The precipitate from the Sunlite tubing did not appear to contain either Tween or PVA because of the absence of a carbonyl absorption which both have. The Sunlite precipitate absorbed more strongly between 1500 and 1200 cm^{-1} than did the extract from our 110X402.  J. W. Ryan ch		
LOG BOOK REFERENCE:		GROUP FILE ACQ. NO.
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TITLE WHITE PRECIPITATE FROM INSIDE OF TUBING USED FOR MEDICAL APPLICATIONS		
AUTHOR R. A. Yount	LOCATION ALTC	DATE 9/22/75
REQUESTED BY: H. H. Marty	LOCATION ALTC	PROJECT NO. 3295
SUMMARY		
Sunlite Plastics make PVC tubing used for medical applications. They use G-92 resin in their compound formulation. In tests run by Sunlite Plastics, a precipitate was found on the inside walls of the tubing. Their customer, American Hospital Supply, analyzed the precipitate and said it was glycol monostearate. We use Span 60 (sorbitan monostearate) in the production of G-92 resin. We need to know if this is being extracted from the tubing. Samples of precipitate from a bottle made from compound using G-92 resin and from two samples of tubing from Sunlite Plastics were analyzed. Infrared absorption spectrometry, x-ray fluorescence spectrometry and mass spectrometry were used to analyze the precipitates. The evidence is considerable that Span 60 (sorbitan monostearate) is being extracted by water or any water solution. We need to tell our customers that they should not use G-92 in any application where water blush would be a problem. <u>Discussion</u> G-92 resin is used in Sunlite Plastics' formulation of compound from which they make PVC tubing for medical applications. In two tests performed by Sunlite Plastics, they found a white precipitate on the inside walls of the tubing. Before we received the tubing samples, the sales group found a bottle made from Geon 83408 (G-92) Compound that had a precipitate on the inside walls. It was submitted for analysis in the hope that this precipitate would be the same as the one found by Sunlite Plastics. This bottle had been filled with tap water and after a period of time a precipitate appeared on the inside surface. The material was scraped from the inside of the bottle and analyzed by Jack Ryan using infrared absorption spectroscopy. He found that 80 to 90% of the precipitate was a salt of a fatty acid, probably stearic acid, and the other 10 to 20% was an ester that could be sorbitan monostearate (Span 60). X-Ray fluorescence spectroscopy analysis of the precipitate showed only one major component, calcium, and a small amount of iron. The bottle compound contains a calcium-zinc phosphite stabilizer, but, no zinc or phosphorus was found. So, the calcium and iron probably came from the tap water.		
LOG BOOK REFERENCE:		GROUP FILE ACQ. NO.
DISTRIBUTION:		
CTF L. B. Crider J. L. Dorsch F. E. Krause M. M. O'Mara J. W. Ryan A. L. Schultz		

H. H. Marty
September 22, 1975
Page Two

Test samples of tubing, similar to the ones that Sunlite Plastics had tested, were sent for our examination. One sample contained a dextrose and sodium chloride solution and the other contained a sodium bicarbonate solution. They both had a white floc suspended in the solutions. Samples of the solutions were centrifuged to collect the floc. Part of the samples of floc was examined by x-ray fluorescence spectroscopy. Only a small amount of chlorine was seen, primarily, in the floc from the dextrose/sodium chloride solution and is probably due to the sodium chloride. The samples were examined by infrared absorption spectroscopy. The sample from the dextrose solution showed interference from the dextrose. So the other sample was washed with distilled water and centrifuged. The infrared spectrum was run by John Dorsch, who said that it appeared to be the sorbitan monostearate. In order to confirm that it was the sorbitan monostearate (Span 60), mass spectrometer analysis was performed. The spectrum of the unknown was compared to a spectrum of sorbitan monostearate. The high mass ions indicative of sorbitan monostearate are m/e 267, 341, 369, 371, 385, 403, 413 and 431. These are all found to be present in both spectra as can be seen in Figure 1. This data, along with the infrared absorption spectrum, gives good confirmation that the sorbitan monostearate is being extracted from the tubing.


R. A. Yount

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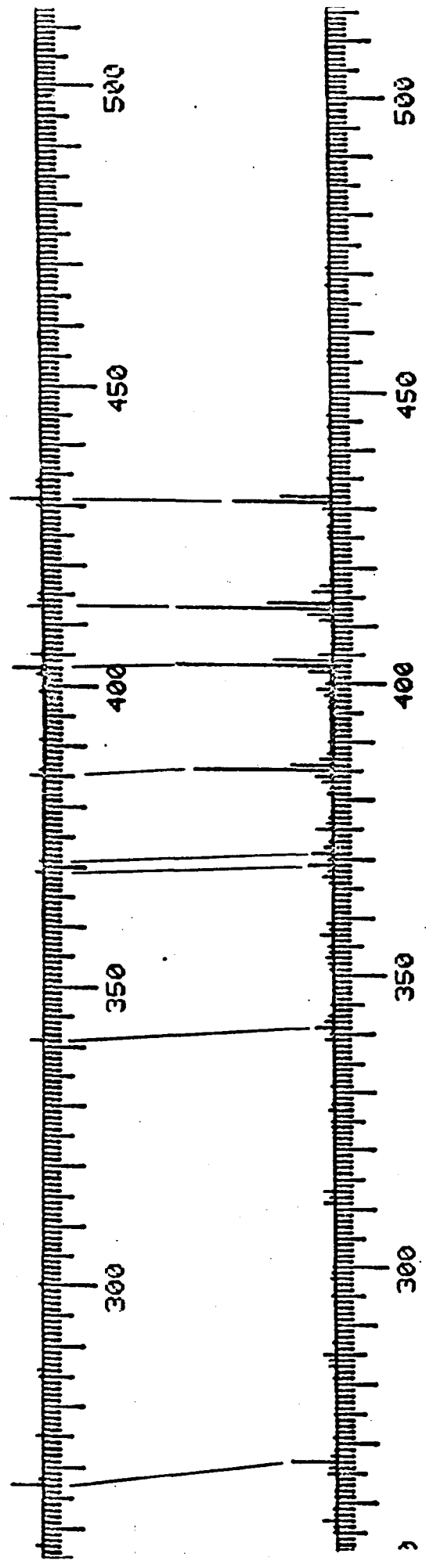
Attachments

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Figure 1

Floc from Sodium Bicarbonate Solution



Sorbitan Monostearate

COMPANY-CONFIDENTIAL

TO	F. E. Krause	FIELD POINT OR DEPT. & BLDG. NO.	Avon Lake Technical Center	DATE YOUR LETTER
FROM	G. F. Cohan	FIELD POINT OR DEPT. & BLDG. NO.	Cleveland/5401	DATE THIS LETTER
SUBJECT	SUNLITE			JUL 29 1975

On 7/14/75, Lars Larsen called from Chicago asking that we call Eli Ostoich (414/383-5975) to discuss a precipitate they were getting in tubing made from Geon 92. I called that afternoon, but he had left for the day. Tom Williams called Ostoich on 7/16/75 and learned the following:

They have supplied medical tubing for about a year to American Hospital Supply using the following ingredients in the formulation.

Geon 92	100
DOP	?
Zinc Stearate	24 gms/100 lbs. PVC

No other ingredients are used.

Tubing made from this formulation was carefully filled with saline solution to eliminate air, pinched off, and let stand for 24 hours at room temperature.

Solution #1 -- 5% dextrose
0.2% sodium chloride

Solution #2 -- 5% sodium bicarbonate

A white precipitate appeared in each case. American Hospital analyzed it as glycol monostearate. No precipitate was found in tubing made with Borden 47-B

Hugh Marty indicated that we use Span 60, sorbitan monostearate, as a dispersing agent in Geon 92. We have always used this, though the amount differs in the plants (1.0 parts per hundred VCM at Avon Lake and 0.7 parts per hundred VCM at Louisville). On January 1, 1975, we started to use Glyconol S at Avon Lake. This is presumably chemically the same as the Span 60 which is still used at Louisville.

The supplier of Span 60, ICI-USA, says the material is acceptable for use in food contact applications. According to Hugh Marty, Span 60 is soluble in vinyl chloride but not in water.

Tom Williams and Hugh Marty called Wally Bachtel who confirmed that sorbitan monostearate was acceptable in food contact applications. As far as subcutaneous contact is concerned, such a precipitate might obstruct flow in intravenous feeding and thus be objectionable from this standpoint, but we are not aware of any other potential adverse

effects at this time.

Clear compounds made from Geon 92 have always been subject to water blush which later disappears on drying. Geon 92 has now been ruled out of this application, and we have lost the business. The questions in Sunlite's mind are, "What caused the precipitate? Has there been a change in the resin? Is there any liability involved?"

On 7/21/75, Gene Slingluff called me indicating they had to scrap 31,000 pounds of tubing and, though they were not blaming BFGCC, they had to explain the cause to American Hospital Supply. I told him we did use a dispersing agent similar in nature to the material reported in American Hospital Supply's analysis but that it had always been there and had not changed. I pointed out that Geon 92 had always been subject to water blush, and our technical people have so stated when water contact is involved with clear compounds. Not so according to Gene who insisted that our sales people have touted 92 as the ultimate in PVC resins. Nevertheless, Sunlite has always run a water blush test evaluating the ultimate clarity after a specific drying period. They have been satisfied on this point. Gene did mention that, when the tubing is filled with plain water, no precipitate is found. He said they wanted to continue to do business with Goodrich, but he needed an explanation and a product. I suggested that 103EP would be satisfactory, and he raised the question of gels. I noted that we have made a change in 103EP and that the number of fisheyes is significantly less today.

Please confirm the extraction of sorbitan monostearate in one of the previously mentioned solutions versus water either from resin or from clear tubing. We should be able to find small samples of tubing made with 92 and 103EP, though the plasticizer systems would differ.

We do owe the customer an explanation and must advise any other accounts in our literature if Geon 92 should be avoided in medical tubing.


G. F. Cohan

GFC/cam

cc: W. C. Bachtel ✓
D. G. Kuharik
A. T. Kukic
L. C. Larsen
J. F. Malone
H. H. Marty
D. A. Savage
G. D. Schaaf
G. A. Small
W. M. Smith
T. W. Williams
File (2)

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