BASIS

BFGoodrich INTER-ORGANIZATION CORRESP

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TO	FIELD POINT OR DEPT & BLDG NO	DATE YOUR LETTER
A.S. Pazur	Avon Lake T.C.	
FROM	FIELD POINT OR DEPT & BLDG NO	DATE THIS LETTER
W.C. Bachtel	Akron - D/0020, 5-H	9-1-83

SUBJECT

Geon 30 - Phenol Extractables

This is to summarize our conversation regarding extractable phenols from PVC resins or compounds for NSF and FDA uses as outlined in your report of 8-24-83.

I believe the NSF phenol limits were derived from the U.S. Public Health Service (now EPA) drinking water standards. The phenol standard was first established in 1946. The standard of 1 ug/l of phenol in water was established on the basis of the undesirable taste often resulting from chlorination of water containing extremely low concentrations of phenols, many of which are natural occuring. For this purpose, the term phenol is understood to include cresols and xylenols. The standard was not set on the toxicity of these materials since, in general, the concentrations injurious to health are far removed from those which impart unpleasant taste.

I know of no FDA limitation for extractable phenols from food contact articles. The only provisions that apply in such a situation are found under 174.5 "General Provisions Applicable to Indirect Food Additives". Essentially this regulation, in part, states that any substance used as a component of a food contact article shall be of a purity suitable for its intended use, also that any food contact article may not impart an odor or taste to a specific product.

In this instance I believe Geon 30 or PVC resins shortstopped with Bisphenol A are of a purity suitable for the intended use so long as Good Manufacturing Practice (GMP) is used to keep the phenolic impurities as low as possible. The values given in your report undoubtedly do not represent all intended conditions of use; however, values at these levels are not too alarming. The second factor to consider is - if these levels impart an off-odor or taste to the food contacted. If they do at any level, then regardless of other considerations, they are unacceptable. I do not believe these levels would have such an effect on food.

There are no specific limitations for phenols in plastic medical products of which I am aware. The USP-NF "Physico-Chemical Tests for Plastic Containers" does not include a test or limit for phenols.

Consequently, I do not see any particular problems with the use of Bisphenol A shortstopped PVC resins for use in food contact articles or medical applications so long as GMP is used to keep the levels of phenol as low as possible, i.e. at or below those values reported.

Obviously there is a problem with the NSF limitation, regardless of what the limitation is based upon. In this case, so long as NSF maintains that limit, then such PVC resins will not be able to be used based on the results in your report.

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BFG 3956-E 1180 (10-70) U.S.A.

If you have further questions, please contact me.

W. C. Bachtel

W. C. Bachtel

v

cc: G.A. Small, ALTC
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BFG TECHNICAL DOCUMENT

THE BF GOODRICH COMPANY CHEMICAL GROUP — REPORT

AUTHOR	LOCATION	DATE	LOG BOOK REFERI
A. S. Pazur	ALTC	8/24/83	111-57-55
REQUESTED BY:	LOCATION	PROJECT NO.	GROUP FILE ACQ. NO.
G. A. Small	ALTC	4131-0113	

SUBJECT -

GEON 30 - PHENOL EXTRACTABLES

INTRODUCTION

Hoffman produces a flexible pipe compound from Long Beach Geon 30. Their customer using this compound to extrude the pipe has been failing NSF phenol extraction tests on that pipe. Hoffman asked us to confirm that the customer's pipe was indeed above the NSF limits on phenol extractables. In addition to testing the pipe, we decided to test one of our own (FDA) compounds made with Long Beach Geon 30, to determine if the bis-phenol A (BPA) shortstop sometimes used with Geon 30 at Long Beach could be affecting the phenol extraction results. To accomplish this, we obtained from Long Beach Geon 30 samples both with and without the bis-phenol A shortstop. We produced Geon 86155 plaques using both these resins for testing along side the customer's pipe.

CONCLUSIONS

1.) The pipe showed phenol extractables at levels twice the NSF limit, confirming the NSF results.

2.) The use of bis-phenol A shortstopped resin results in compound with phenol extractables significantly above the NSF limits.

3.) Even with the use of non-shortstopped resin, our Geon 86155 apparently contains sources of phenol which put it at the limit of NSF acceptability.

RECOMMENDATIONS

1.) Bis-phenol A shortstopped resin should not be sold to accounts selling into NSF, FDA or medical markets.

2.) Suppliers of raw materials used in FDA compounds should be approached regarding phenol levels in those raw materials.

FUTURE WORK

1.) Samples of resins from a plant not using BPA will be analyzed to determine if the phenol found in the non-shortstopped Long Beach resin is a BPA residue contaminating non-shortstopped charges in some manner.

2.) To determine if the reactor coating may be a source of phenol, a sample of a resin not employing a reactor coating or BPA shortstop will be analyzed.

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RESULTS AND DISCUSSION

Hoffman supplied lengths of spiral-wound flexible pipe manufactured by Pacific Echo. This pipe was extruded from Hoffman Long Beach Geon 30-based compound. These were supplied to D.A. Ernes for testing according to the NSF specified phenol extractions test.

Samples of Geon 30 resin were received from Long Beach with the following identification:

Resin Sample A - Geon 30, regular charge, 5/9/83, 22/135
Resin Sample B - Geon 30, shortstopped, 5/9/83, PA#130

Geon 86155 White 136 plaques were made from both using the standard 2 roll mill cycle (7 minutes band time at 325°F). The mill sheet was then pressed for 5 minutes at 345°F. Geon 86155 is a standard FDA hose compound containing only phthalate plasticizer, epoxidized linseed oil, Ca/Zn stabilizer, TiO_2 and a low level of blue tint masterbatch.

The plaques were also supplied to D.A. Ernes for testing with the pipe. The test method and his results are detailed in BFG Technical Document entitled "Phenol Extractables From Flexible PVC Pipe", D.A. Ernes/ J. N. Lindway to A. Pazur/E. Williger, 8/5/83. These results are summarized below:

	PHENOL CONCENTRATION (ppb)
Black pipe	192
White pipe	119
Geon 86155 with non-shortstopped Geon 30	56
Geon 86155 with shortstopped Geon 30	332

The NSF limit is 50 ppb. Besides confirming NSF test results on the Pacific Echo pipe, these results show that the BPA shortstop can significantly affect phenol extraction levels. In addition, one or more of the other raw materials used in the Geon 86155 apparently contain extractable phenol.

A. S. Pazur

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