

TO	R.W. Tannehill	FIELD POINT OR DEPT. & BLDG. NO.	DATE YOUR LETTER
FROM	N.D. Friedberg	(NDF-017-77)	DATE THIS LETTER
SUBJECT	2/11/77		

Discussion with G. Hughmark and G.C. Gaeke of Ethyl Corporation at ALTC on 1/26/77

BFGCC Personnel

E.G. DeCapita
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Ethyl Corporation Personnel

G. Hughmark
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Purpose

The purpose of this meeting was for us to have a chance to review, criticize, and strengthen in any way we can Ethyl's proposed experimental program to establish a VCM non-migration level for PVC bottles (see G. Hughmark's 1/17/77 revised draft). Ethyl is ready to blow the bottles for this program the first week in February 1977. They estimate the program will take 12 weeks to complete including the 2 month's of storage at 120° F. FDA has encouraged Ethyl to proceed.

Discussion

Ethyl says their head space GC method is sensitive to about 5-10 ppb for powder blend bottle compound; once they make pellets, their sensitivity drops off to about 30 ppb. Ethyl does not feel their mass spectroscopy capability is as good as ours and they want us to participate in their program to the extent we wish.

Hughmark reviewed his experimental approach which all of us had previously read over. No one from BFGCC had any serious disagreement with the approach. A key part of the experiment will be to obtain bottle compound with the desired levels of RVCM, with the same heat history, but without severe enough heat history to cause any heat degradation of the PVC. Ethyl feels this can be accomplished by driving off essentially all the VCM by blowing warm air through the PVC, then spiking the resin with VCM (allowing sufficient time to reach equilibrium) to hopefully obtain RVCM levels in the bottle walls of about 0.01, 0.01-0.02, 0.03-0.05, 0.1, 0.3, and 1 ppm. Actually Ethyl will make up two powder blends from the same compound additives other than the PVC resin. One powder blend will contain a high RVCM resin and the other will contain a very low RVCM resin. Portions of the two blends will be mixed to give bottles with the RVCM levels mentioned above. Ethyl has determined that the VCM loss from going from powder blend to pellet is about 10% and the VCM loss from pellet to bottle, another 10-15%. Ethyl will blow enough 16 oz. bottles (about 30g.) for 4 weeks and 2 months storage with aqueous 50% ethanol and with pure water.

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Lin Crider briefly described our recent work with our GC-MS instruments to try to determine the level of detection of GC-MS in various solvents. We have found that MS can confirm VCM in water down to about 15 ppb and in 50% ethanol-water somewhere between 37-55 ppb. Based on the diffusion model, then, we would need bottles containing about 2-5 ppm RVCM in the bottle wall in order to extract sufficient RVCM into water or aqueous ethanol for MS to confirm the presence of RVCM in the extracts. Thus, even the highest level RVCM bottles that Ethyl plans to blow (1 ppm in bottle wall) are not expected to diffuse enough VCM into the media for MS to detect and confirm. Crider et al feel that BFGCC's GC-MS capabilities are about average in the industry although at least one published work (a group in Holland) claims to have MS techniques capable of detection as good as GC head space methods. There was some discussion on whether it would be useful to send some outside group such as a commercial testing laboratory or a university (e.g. S. Gilbert at Rutgers) to try to confirm RVCM by mass spec. at various levels but the general consensus was that there are so many pitfalls (even preparing standard solutions of known concentrations is very tricky) involved that funding such work would not likely produce results that we would have confidence in. DeCapita did describe some work he is doing with Hewlett-Packard to evaluate their GC-MS instrument but this study will not be a part of the Ethyl-BFGCC program.

Action Required

1. It was decided that Ethyl will send A.P. Metzger two sets of empty bottles, a set from near the low end of the RVCM in the bottle wall (0.1 ppm) and a set at the highest RVCM in the bottle wall (~1 ppm). Al will fill one set (about 6 bottles) with aqueous ethanol and the other set with water. After 2 months of storage at 120°F, we will test the extract with head space GC and with MS. Ethyl will provide us with RVCM data on the resin, on the powder blend, and on the cubed compound. *For Ethyl's conversation with Dr. Langemark, to keep with also send us a set of bottles with 2-5 ppm RVCM in the bottle wall.*
2. Lin Crider will write a report describing our work at determining the level of MS sensitivity for analyzing VCM in aqueous ethanol and in water. This report will be ready in about one week. It will contain raw data, MS spectra, the techniques used, and our conclusions that MS will not confirm the presence of RVCM in water below 20 ppb and in aqueous ethanol below somewhere between 37-55 ppb. This report will be sent to me and after review with Cleveland personnel (Malone, Tannehill, Zwicker, Savage) we will send the report to Dixler-Heckman. If Dixler-Heckman agree, we will submit this report to FDA and have someone such as Crider go along with Dixler-Heckman for presenting this work to FDA. It is our and Ethyl's hope that this work will lead to FDA establishing a reasonable non-migration level of RVCM in the bottle wall, or in the resin, as opposed to the other alternative of FDA simply banning the use of PVC bottles as food packages.

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