

HISTORY

1973 Ethyl confirms up to 500 ppm in bottle compounds.

Nov., 1974 Ethyl advises FDA $\leq$ 1 ppm VCM specification by January, 1975, for food-grade bottle compound.

Jan., 1975 Ethyl provides FDA with prediction model for advance determination of maximum potential VCM migration to bottle contents.

Sept., 1975 Ethyl established $\leq$ 1 ppm specification for all bottle compound.

Sept., 1975 FDA publishes proposed ruling:
 PVC Film -- OK
 PVC Plastisols -- OK
 Blister and Bottles -- Questionable

Subsequent studies confirm Ethyl prediction model for maximum potential migration. Actual results 70 to 85% of prediction under accelerated conditions.

1976 Ethyl production of all bottle compound averaged $\leq$ 0.2 ppm VCM for entire year -- ambient storage conditions yield as low as 25% maximum predicted.

Analytical ability (head space gas chromatography) improved to the point that interferences in the low parts per billion range show up.

Jan., 1977 FDA commented on the need of confirmation of VCM by mass spectroscopy.

Jan., 1977 Ethyl proposes to FDA experimental protocol to establish a Non-Migration Level of VCM as confirmed by GC/MS.

May, 1977 Experimental program completed and non-migration level established. Results based on both FID and GC/MS analysis. GC/MS conducted by independent laboratory.

June, 1977 Ethyl proposes continued use of PVC bottles for food packaging at a non-migration level of VCM which ensures there is no reasonable expectation that VCM may become a component of bottle contents under normal conditions of use.