

Heat-induced Extractable Profile Study In PVC film Using Headspace GC/MS Methodology

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Abstract

Polyvinyl chloride, PVC, film has been widely used in medical devices for the last 50 years and satisfied the demanding requirements of the healthcare industry. However, due to health concerns, there is increasing scrutiny of potential extractables and leachables released from PVC container closure systems. A headspace GC/MS methodology is utilized to quickly identify and quantitate the heat-induced extractables from PVC film.

Methods

GC/MS System: Agilent, 6890N GC with MS 5975 inert XL Mass Selective Detector in EI Mode.

Data Analysis Software: G1701DA ChemStation, Revision Code: D.02.00.

Column: J & W Scientific, DB-5ms, 20 m x 0.18 mm ID, 0.18 mm film thickness.

Oven Temperature Program: Initial Temperature 40°C, hold 6 min, 40°C to 300°C at 15°C/min, and hold 5 min.

Total run time: 28.33 min.

Injection Temperature: 250°C. MS detector Temperature: 230°C. Flow rate: 1.0 mL/min.

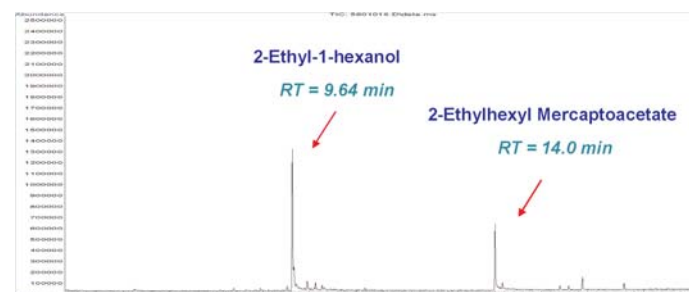
Autosampler: CTC, Combi PAL with incubator.

Incubator Temperature: up to 180°C.

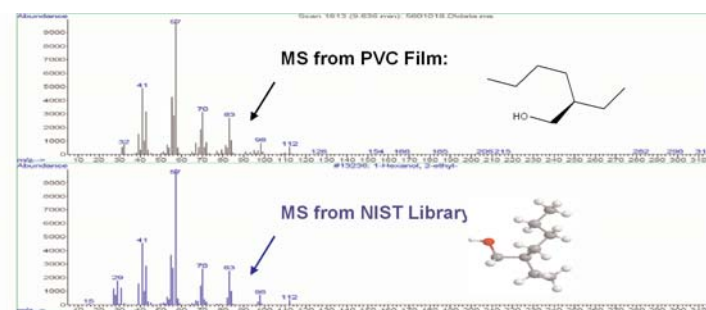
Incubator Time Points: 10, 20, 30, 40, 50, 60 & 120 seconds.

Sample: A 2.5 cm x 2.0 cm section of PVC film placed into a 23 x 46 mm 12- mL headspace vial

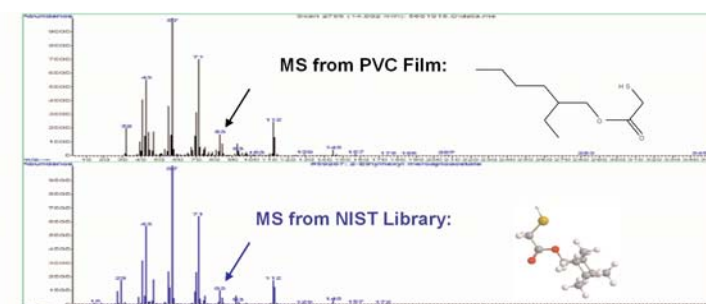
Data



GC/MS Total Ion Chromatogram of Headspace Extractables

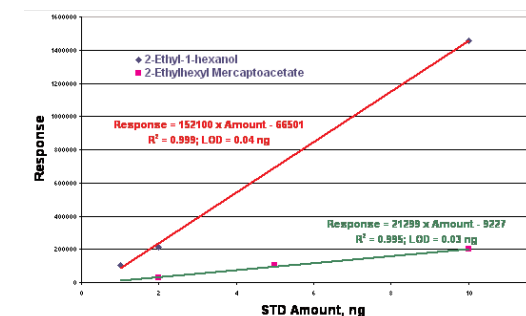


MS Spectrum of 2-Ethyl-1-hexanol @ 9.64 min

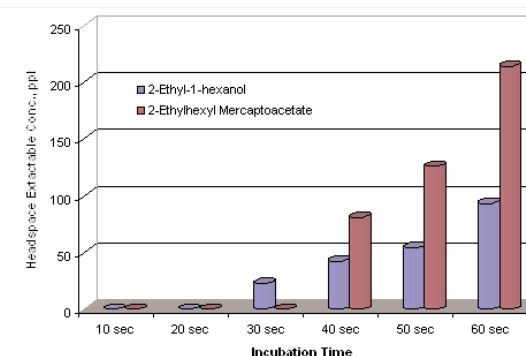


MS Spectrum of 2-Ethylhexyl Mercaptoacetate @ 14.0 min

Results



GC/MS Reference Calibration Curves



Quantitation of Headspace Extractables

Conclusions

This study provides information on the composition of potential heat-induced extractables from a plastic material, e.g. PVC film. The headspace GC/MS is a useful tool to identify, characterize and quantitate potential volatile extractables under certain conditions (headspace, temperature and incubation time).