



LIQUID CHROMATOGRAPHY SPECIALISTS

4 Mill Street
Bellingham, Massachusetts 02019
(508) 966-1301 • Fax (508) 966-4063
E-mail jordiassoc@aol.com • www.jordiassoc.com



July 14, 2003

Mr. Rick Terwilliger
Worldwide Medical Technologies
426 Main Street North
Woodbury, Ct. 06798-0505

Dear Mr. Terwilliger:

Two Bone Wax samples were submitted for FT-IR, NMR and PYMS analyses and photographic documentation.

FT-IR Results

The FT-IR results showed the samples to be a polyethylene similar to Dislon 4200-10.

Polyethylene is a high molecular weight polymer formed by the polymerization of $\text{CH}_2=\text{CH}_2$ at 200°C and 15,000-20,000 psi in the presence of O_2 traces. The principal absorbance bands appear near 2900 cm^{-1} due to the C-H stretch and 1470 cm^{-1} due to CH_2 deformation vibration with a characteristic strong sharp doublet in the $730\text{-}700\text{ cm}^{-1}$ region indicating the CH_2 rocking motion. The doublet is only present when there are crystalline ethylene units present in polyethylene. Only one band is observed for amorphous polyethylene.

I had to search but eventually found an FT-IR spectrum of beeswax (chart 10) which does look like the spectra of both your bone wax standard sample (chart 1) and your needle pug material (chart 5). Chart 9 is an overlay of the FT-IR spectra of your bonewax and your needle pug materials which demonstrates that they appear to be virtually identical via FT-IR spectroscopy.

For analysis your samples were placed on a DuraScope, which is an integrated video imaging accessory and scanned with a Perkin Elmer PC-16 FT-IR instrument. The DuraScope is a diamond ATR system for the analysis of all samples.

Enclosed you will find the FT-IR spectrum, peak assignments, and a reference spectrum of Dislon 4200-10.

NMR Results

Enclosed please find a ^1H and ^{13}C NMR spectra of samples Bonewax Standards and Worldwide Technologies Sample Bonewax Non-Sterile Needle Plugs, obtained in benzene- d_6 solution on the 400-1 instrument.

The ^1H NMR spectra are almost identical; there are some minor differences, but all the differences together are only about 0.1% of the total. The ^{13}C NMR spectrum of the Needle Plugs was relatively weak, due to the limited sample. The peaks observed in the spectrum are also observed in the Bonewax Standard, but the small peaks that are observed in the latter spectrum are hidden in the noise of the Needle Plugs spectrum. In order to obtain an equivalent spectrum we would have to have more material or obtain data for a longer period; given the ^1H NMR data, this may not be necessary.

One small difference between the samples showed in the sample preparation. The bonewax Standard totally dissolved, but there was some insoluble material in the Needle Plugs; it looked like fibers.

Digital pictures were obtained of the instrument (SDS400-1), and two each of the samples being inserted into the instrument.

PYMS Results

Analytical Procedure:

The Bonewax non-sterile needle plugs (Worldwide Technologies) and the Bonewax standard were submitted for analysis by pyrolysis mass spectrometry (PYMS). In this procedure the sample is heated from room temperature to 540°C at 40°C per minute while mass spectra are continuously recorded. This analysis is expected to identify components that can be volatilized or pyrolyzed.

Results:

Both samples gave strong spectra for the following components:

- Isopropyl palmitate
- Parafin wax*
- Triacetyl and Hentriaconyl palmitates*

**Components of Beeswax*

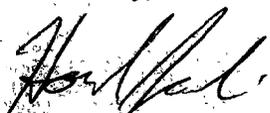
The Bonewax non-sterile needle plugs (Worldwide Technologies) sample also showed an unidentified component with a probable molecular weight of 368. This component was not detected in the Bonewax standard sample. Further work will be required to try to ID the 368MW component and even then it may not be possible to identify it. Looking at the intensity curves, it is also possible that it is related to the insoluble fibers seen in the NMR dissolution work.

Conclusion

Both your Bonewax non-sterile needle plugs and your Bonewax standard looked virtually identical via FT-IR, NMR and PYMS. If you wish to try to ID the low level fibers seen only in your Bonewax non-sterile needle plugs, I would suggest obtaining several packages of fresh needle plugs, dissolving the plugs in methylene chloride, filtering to recover the insolubles and then running an FT-IR, NMR and PYMS of the insolubles.

Thank you for allowing us to be of service. Please call if you have any questions.

Sincerely,



Howard Jordi, Ph.D.