

45 Discovery Drive Rensselaer, NY 12144 Ph# 518-432-0617 Fax# 518-432-9146 www.iltusa.com

ULTRA Mass Spec Certified Cap Certificate of Analysis

DATE:

DESCRIPTION: <u>ULTRA MASS SPEC SEPTA ASSEMBLED INTO 9-425 SCREW CAP</u>

LOT NUMBER: *******

Liner Sheet Material:

Testing Performed

• GC/FID Extractable Testing

9 mm Assembled Cap

Testing Performed

- GC/FID Extractable Testing
- GC/MS Extractable Testing
- LC/MS Finished Good Testing

Product has been analyzed by Gas Chromatograph/Flame Ionized Detector, Gas Chromatography/Mass Spectrometry and Liquid Chromatography/Mass Spectrometry

Test Results: The product listed above shows compliance to all applicable specifications

CHEMICAL TEST REPORTS ARE ON FILE WITH US OR OUR SUPPLIERS FOR EXAMINATION AND REVIEW



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CERTIFICATE OF ANALYSIS

DATE:	ILT PART #:	LOT #:	
Product has been tested for the following comp		ll Volatile Organic Quantitat	ion limits specified
<u>Compound</u>	Quantitation Limit (µg/L)	Compound	Quantitation Limit (µg/L)
Acetone	< 5.0	Hexachlorobutadiene	< 0.5
Acrylonitrile	< 1.0	2-Hexanone	< 5.0
Benzene	< 0.5	Iodomethanc	< 0.5
Bromobenzene	< 0.5	Isopropylbenzene	< 0.5
Bromochloromethane	< 0.5	m+p Xylenes	< 0.5
Bromodichloromethane	< 0.5	Methyl Acetate	< 1.0
Bromoform	< 0.5	4-Methy-2-pentanone (MIBK)	< 5.0
Bromomethane	< 0.5	Methyl-t-butylether (MTBE)	< 0.5
2-Butanone (MEK)	< 5.0	Naphthalene	< 0.5
Carbon Disulfide	< 0.5	n-Butylbenzene	< 0.5
Carbon Tetrachloride	< 0.5	Nitrobenzene	< 0.5
Chlorobenzene	< 0.5	n-Propylbenzene	< 0.5
Chloroethane	< 0.5	o-Xylene	< 0.5
Chloroform	< 0.5	p-Isopropyltoluene	< 0.5
Chloromethane	< 0.5	sec-Butylbenzene	< 0.5
2-Chlorotoluene	< 0.5	Styrene	< 0.5
4-Chlorotoluene	< 0.5	tert-Butylbenzene	< 0.5
cis-1,2-Dichloroethene	< 0.5	Tertiary amyl methyl ether (TAME)	< 3.0
cis-1,3-Dichloropropene	< 0.5	Tertiary butyl alcohol (TBA)	< 2.0
1,2-Dibromo-3-chloropropane	< 0.5	1,1,1,2-Tetrachloroethane	< 0.5
Dibromochloromethane	< 0.5	1,1,2,2-Tetrachloroethane	< 0.5
1,2-Dibromoethane (EDB)	< 0.5	Tetrachloroethene	< 0.5
Dibromomethane	< 0.5	Toluene	< 0.5
1.2-Dichlorobenzene	< 0.5	trans-1,2-Dichloroethene	< 0.5
1.3-Dichlorobenzene	< 0.5	trans-1,3-Dichloropropene	< 0.5
1.4-Dichlorobenzene	< 0.5	1,1,2-Trichlorotrifluororethane (CFC-113)	< 0.5
1.1-Dichloroethane	< 0.5	1,2,3-Triehlorobenzene	< 0.5
1,2-Dichloroethane	< 0.5	1,2,4-Trichlorobenzene	< 0.5
1,1-Dichloroethene	< 0.5	1,1,1-Trichloroethane	< 0.5
Dichloromethane	< 0.5	1,1,2-Trichloroethane	< 0.5
1,2-Dichloropropane	< 0.5	Trichloroethene	< 0.5
1,3-Dichloropropane	< 0.5	Trichlorofluoromethane	< 0.5
2,2-Dichloropropane	< 0.5	1,2,3-Trichloropropane	< 0.5
1,1-Dichloropropene	< 0.5	1,2,4-Trimethylbenzene	< 0.5
Diisopropyl ether (DIPE)	< 1.0	1,3,5-Trimethylbenzene	< 0.5
Ethyl Acetate	< 1.0	Vinyl Acetate	< 0.5
Ethyl tertiary butyl ether (ETBE)	< 3.0	Vinyl Chloride	< 0.5

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< 0.5

< 5.0

Ethylbenzene

Octa methyl cyclo tetrasiloxane (D4)

<u> Chrystal McDuffie</u>

Deca methyl cyclo pentasiloxane (D5)

<5.0

Authorized Signature Chrystal McDuffie, Laboratory Manager

Headspace Test Method for GC/MS

1. INTRODUCITON

The purpose of this document is to outline the procedure to test 20mm headspace crimps and septa for contamination. Included are the methods, instrumentation, and test parameters.

2. OVERALL TEST PLAN

The 20mm headspace crimps and septa are tested on a TurboMatrix HS-Trap, PerkinElmer Clarus 600T GC/MS system. The analysis is a general method for testing contamination on 20mm crimps and septa by GC/MS. All samples are prepared and analyzed simultaneously with blanks and standards.

3. EXPERIMENTAL CONDITIONS

GC Conditions:

Gas Chromatograph:	PerkinElmer Clarus 600		
Analytical Column:	Elite-624 (60 m x .25 mm id x 1.4 um df)		
Injection Port:	CAP		
Injector Temperature:	110C		
Oven Program:	Temperature	Hold Time	Rate
	40C	2 min.	10C/min
	100C	0 min.	30C/min
	240C	7.33 min.	END

HS Conditions:

115 Conditions.	
Headspace Unit:	TurboMatrix HS-Trap
Headspace Mode:	Trap
Needle Temperature:	100 C
Transfer Line Temperature:	110 C
Oven Temperature:	80 C
Trap Temperature(Low):	40 C
Trap Temperature (High):	280 C
Dry Purge Time:	5 min
Trap Hold Time:	6 min
Desorb Time:	0.5 min
Thermostat Time:	60 min
Vial Pressurization Time:	1 min
Vial Decay Time:	2 min
Column Pressure:	25 psig
Vial Pressure:	35 psig

Desorb Pressure:	10 psig
Outlet Split:	On
Injection Mode:	Time
Transfer Line Type:	Fused Silica 0.25mm id
Headspace Connection Type:	Direct Connection
Trap Packing Type:	Air Toxics

MS Conditions:

Mass Spectrometer:	PerkinElmer Clarus 600T
GC Inlet Line Temp:	180C
Ion Source Temp:	150C
Function Type:	Full scan
Full Scan Range:	35 - 400 m/z
Full Scan Time	0.25 sec
Inter-Scan Delay:	0.02 sec

4. SAMPLE PREPARATION

Use clean certified 20 mL vials for all samples, blanks and standards.

Each vial will be sealed with a 20mm headspace crimp and septa for analysis. Test three caps per lot sampled. All crimps will be assembled on empty vials.

All blanks and standard vials will be prepared immediately before analysis.

5. BLANK PREPARATION

Blanks will be prepared using the vial preparation described above and capped using 20mm crimps and septa that are known and validated to be clean.

Three blank vials should be prepared for every sequence run.

6. STANDARD SOLUTION PREPARATION

A standard solution is made with Iso-propanol, Benzene, Toluene, m + p - Xylene and o - Xylene. The solution is prepared at a concentration of 100 nanograms per microliter (ng/ μ l) for all analytes. This solution must be kept sealed in a dark and cold place.

The standard vial will be prepared by adding 1 μ l of standard solution to the vial for a 100 ngs per analyte concentration.

One standard vial should be prepared for every sequence run.

7. ANALYSIS

Each vial will be analyzed under the conditions given in section 3. The chromatograms will be examined against the standards. Any peak detected associated with the peak in the standard will be identified and quantified.

The first four vials analyzed will be in the order or Blank, Standard, Blank, Blank.

Samples, standards and blanks can only be run on time – multiple injections from the same vial are not valid.

A quantitative report will be produced that lists the identity and amounts of any contaminant peak detected in the chromatograms for every sequence run.

Headspace septa have the following specifications:

All PTFE/Silicone and PTFE/Butyl septa:

Iso- Propanol	< 50 ngs
Toluene	< 10 ngs
Benzene	< 10 ngs
m + p - Xylene	< 10 ngs
o – Xylene	< 10 ngs

All Butyl septa:

Iso- Propanol	< 200 ngs
Toluene	< 200 ngs
Benzene	< 200 ngs
m + p - Xylene	< 200 ngs
o – Xylene	< 200 ngs