

Extractable and Leachable Testing of Electronic Nicotine Delivery Systems

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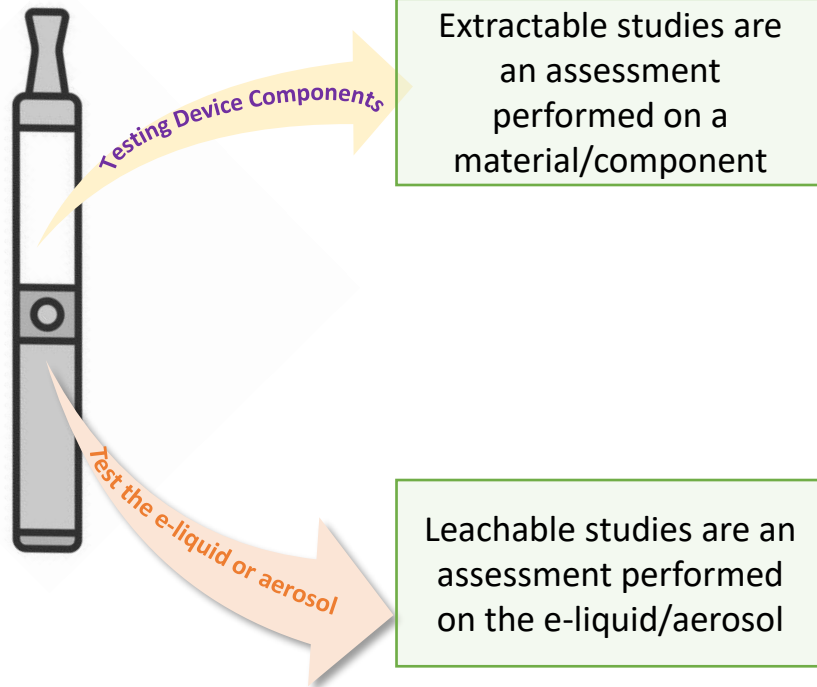
E&L: Definitions

- **What are Extractables?**

Chemical substances that migrate from a component/material under laboratory conditions. These conditions are generally designed to accelerate/exaggerate normal use/storage conditions.

- **What are Leachables?**

Chemical substances that migrate under normal use/storage conditions into the e-liquid/aerosol or through direct contact with the consumer.



Analytical Techniques



Volatiles
HS-GC-MS



Semi-Volatiles
GC-MS



Non-Volatiles
LC-MS



Inorganics
ICP-MS

Compounds of Concern

- Phthalates
- Polycyclic aromatic hydrocarbons (PAHs)
- Metals
- Formaldehyde
- Nitrosamines
- Bisphenol A
- Mercaptobenzothiazole

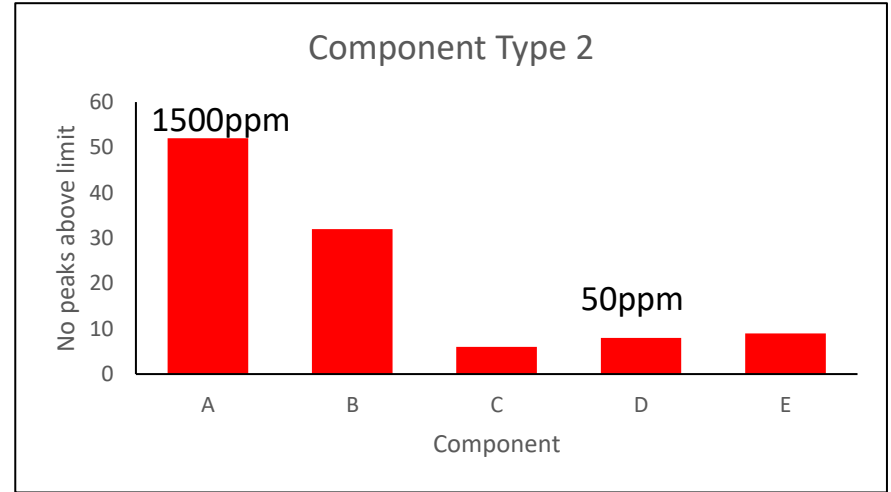
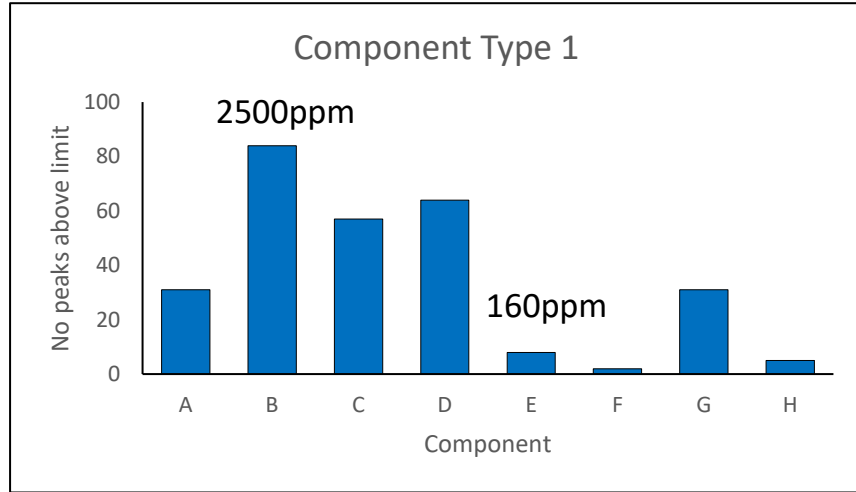


Material Selection – Case Study 1

- Two components
 - Multiple base polymers, suppliers and grades
- Extraction Method
 - HS-GC-MS Solid sample incubation for 30 mins at 60 °C
 - DI-GC-MS & LC-DAD-Qtof - 4 hour Soxhlet extraction in ethanol
- Analytical Techniques
 - HS-GC-MS
 - DI-GC-MS
 - LC-DAD-Qtof

Material Selection – Case Study 1

Same component, different suppliers – The number of extractables and levels observed vary widely



Extraction Study – Case Study 2

MATERIAL CHARACTERIZATION

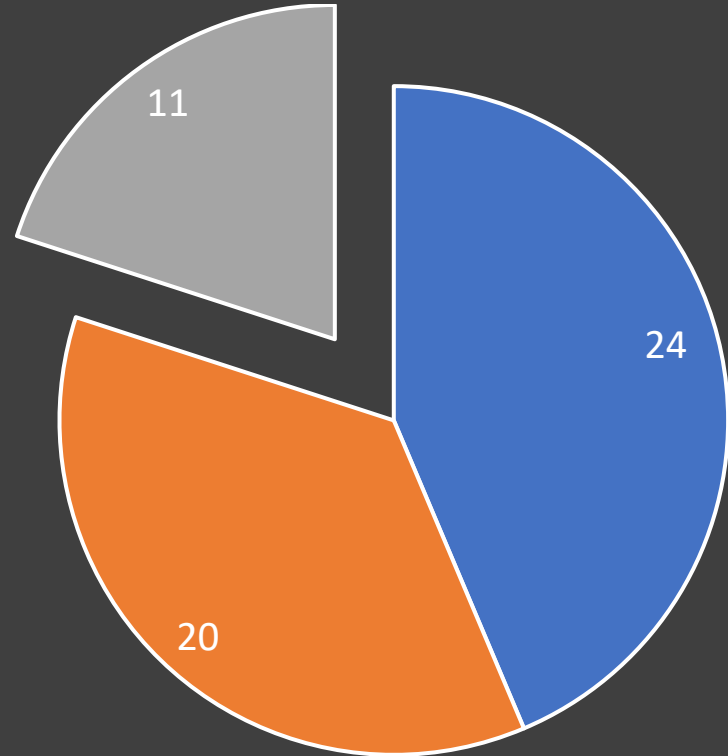
- Solvents
 - pH 4 adjusted IPA/Water & pH 9 adjusted IPA/Water
- Extraction Methods
 - Reflux, RT Sonication & Sonciation at 75 °C
- Extraction Time:
 - 4 hours
- Techniques
 - DI-GC-MS (Polar & Non-Polar Columns)
 - LC-DAD-Qtof

IN-USE SIMULATION

- Solvent
 - PG/VG/Nicotine/Water
- Extraction Methods
 - Reflux, RT Sonication & Sonciation at 75 °C
- Extraction Time:
 - 4 hours
- Techniques
 - DI-GC-MS (Polar & Non-Polar Columns)
 - LC-DAD-Qtof

Extraction Study – Case Study 2

- Phenylmorpholine
- Irganox 1010 degradant
- C20H32O5
- C10H10O2
- 2,2'-(Tridecylimino)bisethanol
- 2,2'-(pentadecylimino)bisethanol
- Hexadecanoic Acid
- Octadecanoic Acid
- Irganox 1010
- Hexadecyl 3,5-di-tert-butyl-4-hydroxybenzoate
- Phenylmorpholine related

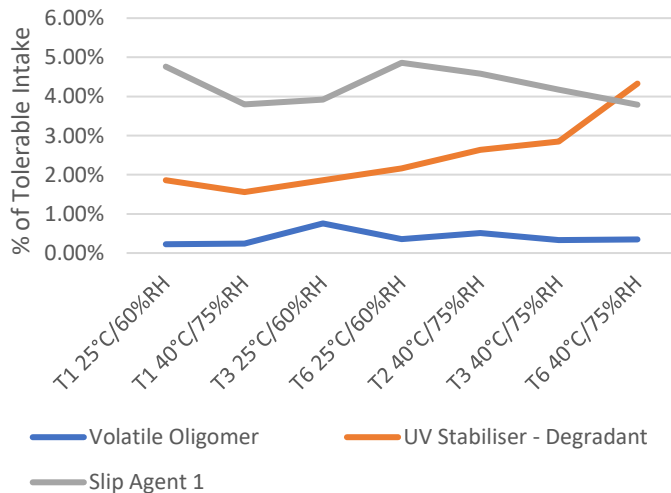


Leachable Study – Case Study 3

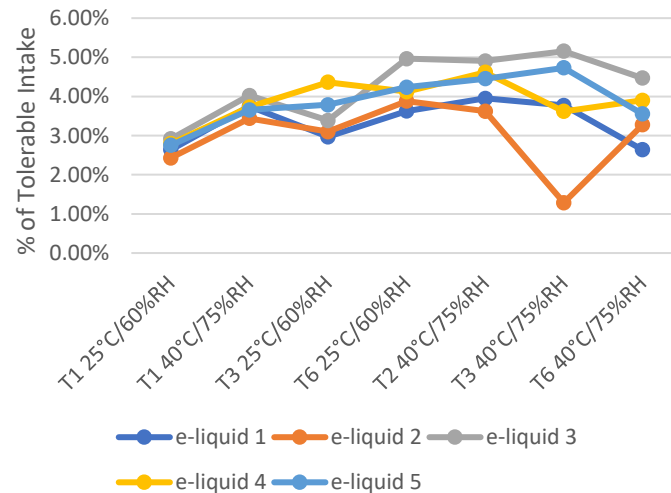
- Multiple flavours
- Two storage conditions – Shelf life and Accelerated
- Up to 24 months storage
- Validated targeted methods
 - HS-GC-MS
 - LC-DAD-Qtof
 - ICP-MS
- Non-targeted screening methods
 - HS-GC-MS
 - DI-GC-MS
 - LC-DAD-Qtof

Targeted Leachable Study

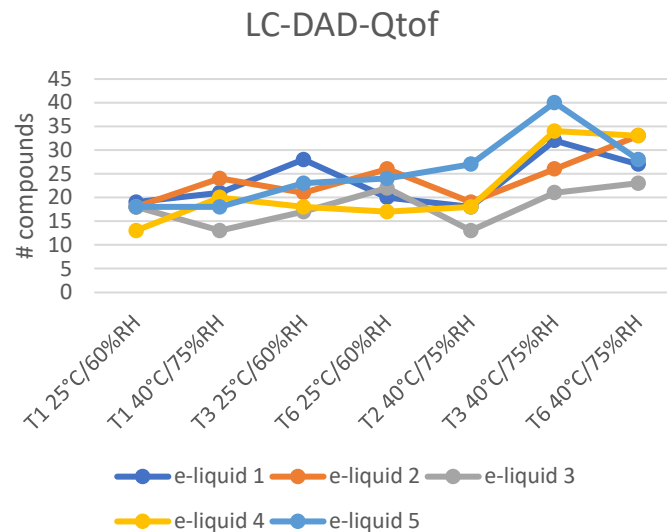
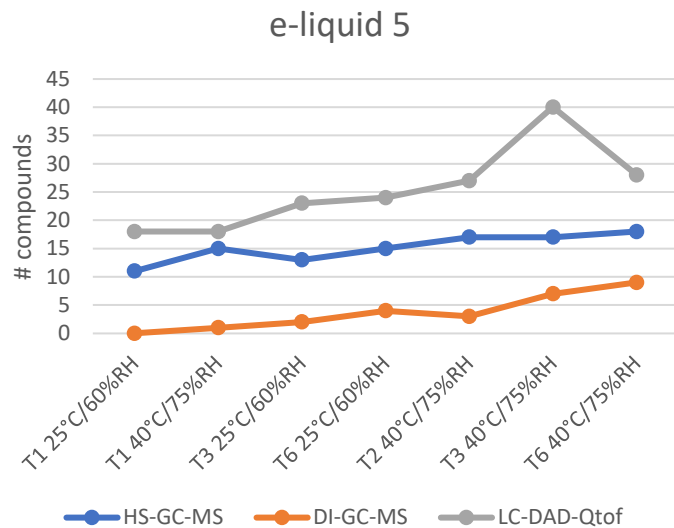
e-liquid 1



Slip Agent 2



Non-targeted Leachable Study



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