

Evaluation of Sustainable Solvents for Extractables and Leachables Analysis

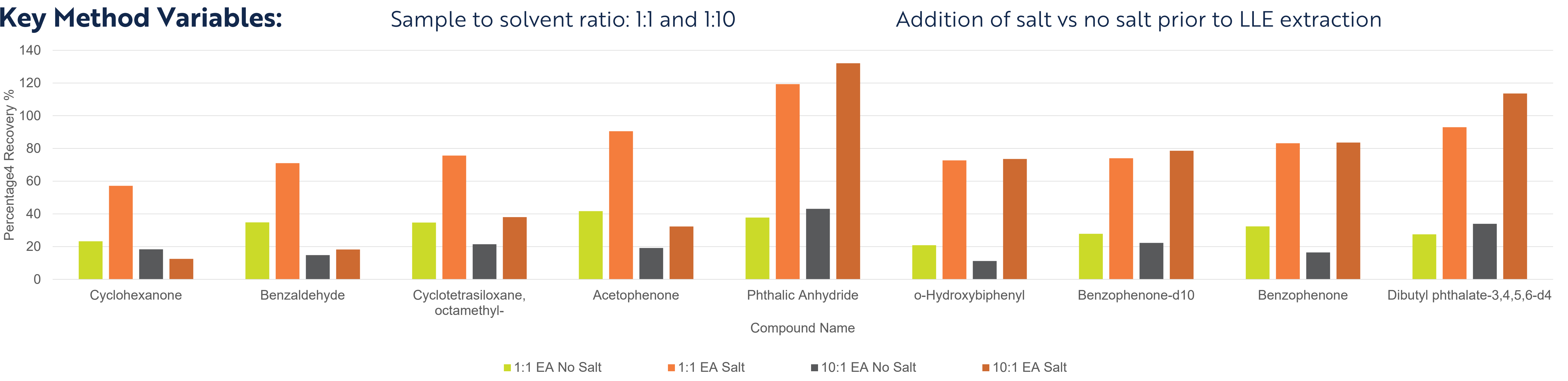
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Introduction

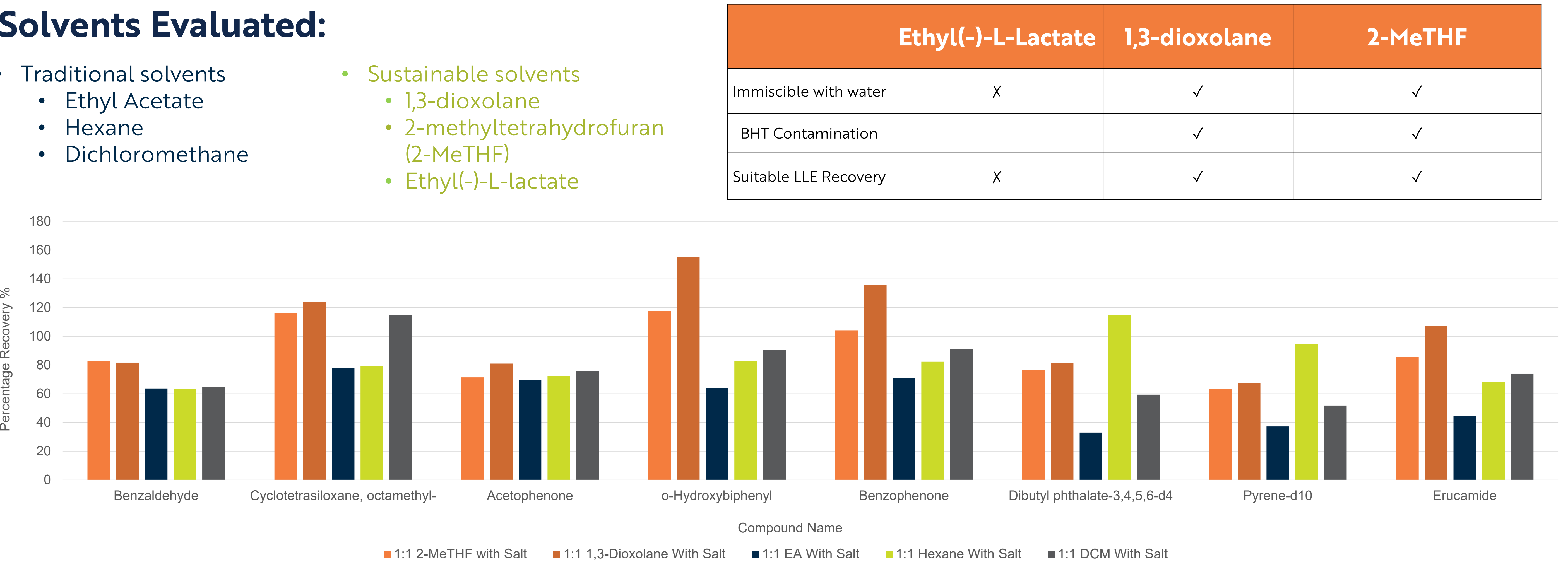
There is an increasing demand to reduce the environmental impact of assays. Sustainable chemistry emphasises the importance of developing processes that minimise the consumption of reagents with a negative impact on people and ecosystems, both during their manufacture and their eventual disposal. The benefits of applying the principles of sustainable chemistry to analytical methods go beyond reducing environmental impact. Updating current analytical methods with a focus on sustainable chemistry aligns with corporate responsibility and brand image and may increase analytical performance. The Extractables and Leachables (E&L) department at Resolian Analytical Sciences utilises gas chromatography mass spectrometry (GCMS) with a 5% phenyl-arylene/ 95% polydimethylsiloxane capillary column to screen for potential volatile and semi volatile impurities in medical devices, pharmaceutical, biopharmaceuticals, consumer healthcare and nicotine delivery products. To ensure compatibility with the GCMS instrumentation for aqueous based matrices, due to their reactivity and high boiling point, the standard practice is to perform liquid-liquid extraction (LLE) with an appropriate organic solvent prior to GCMS analysis.

In response to growing demand for more sustainable practices, this study focuses on the evaluation of the suitability of three sustainable solvents: 1,3-dioxolane, 2-methyltetrahydrofuran and ethyl(-)-L-lactate alongside three traditionally used solvents: ethyl acetate, hexane, and dichloromethane for LLE of one aqueous products. The efficacy was evaluated through the recovery assessment of commonly observed extractable compounds with a varying polarity, boiling point and retention times.

Impact of Sample to Solvent Ratio and Salt Addition



Extraction Efficacy of Traditional and Sustainable Solvents



Conclusions

- Currently there are no suitable sustainable alternatives to the traditional organic solvents used for liquid-liquid extractions in extractables and leachable screening studies.
- 1,3-dioxolane and 2-methyltetrahydrofuran can be a suitable sustainable alternative for targeted leachables studies, if BHT is not of concern. However, this needs to be assessed on a case-by-case basis.
- This work demonstrates the potential viability of sustainable solvents for use in screening E&L studies if manufactures produced solvents with alternative antioxidants.

References

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