THE EMERALD CONFERENCE
Produced by MJBizScience

March 1-3, 2023
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A Framework for Scientifically Deriving Safety Limits for Inhalable Cannabis Concentrates

Speakers: Shawna Vreeke, PhD, Head of Research, True Terpenes & Echoleah Rufer, PhD, Director of Health Services, PAX

Abstract: Inhalable cannabis concentrates have gained popularity in recent years, but there is little guidance for manufacturers or regulators to evaluate additive safety. Without guidance, cannabis manufacturers are left guessing what they should put in their products–and, too often, unaware of the health risks. In addition, lab capabilities and federal regulations make most toxicological testing infeasable. As such, we have developed a framework for first-tier toxicological assessment of vaporized cannabis concentrate additives using new approach methodologies that can be used by individuals without significant toxicological expertise to reject, accept, or prioritize for further evaluation.

Toxicological risk is a function of the inherent toxicity of a substance and the amount someone consumes. For toxicological risk assessment, data on the inherent toxicity of the substance are compiled from peer-reviewed papers, regulatory limits, and guideline studies. The studies are weighted based on relevance, reliability, and quality, with appropriate uncertainty factors applied to derive a safety limit. For exposure assessment (i.e., the amount someone consumes), we have analyzed data from more than 54,000 smart vaporizer devices and published literature to estimate a conservative consumer consumption value that is representative of real-world use that can be used to calculate exposure for risk assessment purposes. This session will review the safety assessment framework, how to derive a safety limit, and go through a real-world example. The purpose of this session is to empower manufacturers and regulators to assess ingredients added to inhalable cannabis concentrates to improve consumer safety.