

ADVANCING INHALATION SAFETY IN THE CANNABIS INDUSTRY



Abstrax®



PRIORITIZING CONSUMER SAFETY

Partnering with Abstrax is not only a commitment to consumer safety and premium quality, but it's also a strategic business decision to de-risk your operations. By entrusting us with your cannabis product ingredient needs, you align with a company that is conducting the **world's most extensive, and comprehensive, cannabis ingredient toxicology study.**

Our **Risk Assessment and Toxicological Evaluation Program (RA-TEP)** aims to finally establish the acceptable ingredient use levels for terpene based flavors used in cannabis products, a novel approach that prioritizes consumer safety over all else. This has never been done before.

Started in 2019, our advanced ingredient review program strives to guarantee the safety of every terpene-based flavor for its intended use - **including inhalation.** This rigorous program, unlike any other in the industry, significantly reduces the risk associated with product safety and regulatory compliance.

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Read on to learn how Abstrax and AVD are creating a safer cannabis industry.

THIRD-PARTY INDEPENDENT EXPERTS

There has been a notable lack of research in light of the rapid growth of inhalable products. And, as such, regulators are sometimes drafting legislation without relying on well-established scientific foundations.

At Abstrax, we have proactively addressed the knowledge gap by **assembling a world-class team of renowned independent third-party Ph.D. experts** from diverse fields, such as inhalation toxicology and analytical chemistry, with over 100 years of combined experience.

OUR TEAM IS DEDICATED TO THOROUGHLY STUDYING THE SAFETY OF CANNABIS INGREDIENTS, INCLUDING TERPENES, WHEN USED IN REAL-WORLD INHALATION SCENARIOS.

Abstrax

AVD
ADVANCED VAPOR DEVICES

McKINNEY
REGULATORY SCIENCE ADVISORS, LLC.

PREVENTING THE NEXT VAPE CRISIS

We all remember the EVALI vaping crisis of 2019. That outbreak caused severe lung injury and even the death of some consumers. **Nobody wants to see that happen again.**

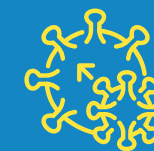
It is therefore imperative to fully evaluate the toxicity of any ingredient used in a cannabis product. That's why we're testing the lipophilicity, mutagenicity, genotoxicity, and cytotoxicity of the ingredients found in cannabis inhalables. What does that mean?



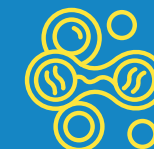
LIPOPHILICITY The ability of a substance to cause lipid pneumonia in the lungs. The lipophilicity of Vitamin E Acetate is what most believe caused the vape crisis of 2019.



MUTAGENICITY The ability of a chemical agent to cause changes in the genetic material of an organism, typically in its DNA, which can lead to mutations.



GENOTOXICITY The property of chemical agents that damage the genetic information within a cell, leading to mutations, which may lead to cancer.



CYTOTOXICITY The ability of a substance to destroy or inhibit the function of cells, which can lead to tissue damage and, ultimately, organ failure if severe.

Be cautious of suppliers who promise to mitigate risks for your business but fail to conduct tests for the very factor that took lives and nearly devastated our industry.

NO OTHER TERPENE SUPPLIER IS TESTING FOR THE FACTORS THAT CAUSED THE 2019 VAPING CRISIS.

It's essential to exercise caution and scrutinize suppliers who may overlook critical testing measures, as they can pose a significant threat to your business' stability and success.

ABSTRAX RA-TEP VS CMR

How does our Risk Assessment and Toxicological Evaluation Program (RA-TEP) compare to other terpene suppliers' Continuous Materials Review (CMR)?

HERE ARE THREE BIG DIFFERENCES:

1 RA-TEP measures the lipophilicity of vape ingredients. The lipophilicity of Vitamin E Acetate is what most believe caused the vape crisis of 2019 and it is completely overlooked in CMR studies.



2 RA-TEP performs direct inhalation studies through a 3rd-party lab. CMR uses an in-house "smoking machine" which can often produce incomplete data and contaminated results. Regulatory authorities typically prefer data obtained from independent laboratories utilizing validated methodologies.



3 RA-TEP also measures the genotoxicity, mutagenicity, and cytotoxicity of cannabis and vape ingredients applied directly to cells similar to human lung tissue. These crucial parameters are also completely overlooked in CMR studies.



BONUS: Our RA-TEP not only evaluated terpene-based ingredients, but also various **flavorants** found in cannabis.

We even assessed the safety of other ingredients commonly found in popular trends, such as "ice" flavors.

We recognize that the industry has embraced a wide range of flavor types and we wanted to ensure that our toxicology program encompassed typical consumer usage, rather than just a few specific use cases.



OUR TEN STEP RA-TEP STUDY

Let's get into the weeds. Here's a detailed analysis of why our approach, modeled after the Pre-Market Tobacco Product Applications (PMTA), is superior.

1 FOCUSED LITERATURE REVIEW
To provide a more accurate and complete understanding of the safety of terpene ingredients used in cannabis products, our program encompasses a broader range of relevant studies and peer-reviewed publications, including toxicological forums and white papers evaluating the toxicity of all ingredients.



2 ADVANCED ALGORITHM FOR EXPOSURE ASSESSMENT
An important component of a Risk Assessment is determining a consumer's exposure to aerosols from product use. To accomplish this, the Abstrax team designed a special algorithm, based on robust consumer use data from multiple manufacturers of inhalable cannabis products. This algorithm enables us to establish guidance use levels for ingredients used in terpene-based flavors intended for inhalable cannabis products.



3 UNBIASED, THIRD-PARTY LAB TESTING
Our RA-TEP research is designed with a team of trained inhalation toxicologists with extensive experience in tobacco and Electronic Nicotine Delivery Systems (ENDS). By employing external, third-party labs to perform the testing, we ensure that our data is free from bias and that our results are reliable, independent, and trustworthy.



4 INDUSTRY STANDARD HARDWARE
Our RA-TEP employs industry standard 510-thread hardware (provided by AVD) for ingredient testing. This offers a more realistic view of the general population's use and exposure. In contrast, ingredient evaluation programs that rely on a single proprietary vape hardware may not capture the full spectrum of user experiences and exposures.



5 INGREDIENT CHARACTERIZATION
Among other things, we measure the lipid solubility of our terpenes. This assay ensures that we effectively avoid ingredients with a lipophilicity similar to those associated with lung injury such as in the vaping lung crisis of 2019.



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AEROSOL ASSESSMENTS

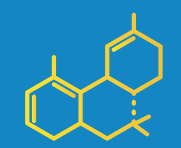


In-house smoking machine experiments and third-party lab studies are not the same. In-house labs often lack the certifications of independent labs, and in-house experiments are typically not conducted using rigorous standards used by independent labs. Moreover, regulatory authorities typically demonstrate a preference for data obtained from independent laboratories utilizing validated methodologies. That's why Abstrax and AVD used a highly reputable independent lab to conduct aerosol chemistry studies. These studies will generate reliable data that will be used to make product decisions and meet the expectations of regulators.

7

REAL-WORLD CANNABINOID TESTING

We conduct thorough testing on Liquid Diamonds (THC with improved purity and stability) and common THC distillate (85%-95% potency) combined with terpenes to simulate real-world consumer usage.



8

BIOLOGICAL ACTIVITY ASSESSMENT



Our RA-TEP measures potential genotoxicity, mutagenicity, and cytotoxicity of our ingredients. This allows us to better understand the potential impact of cannabis ingredients on human health at extreme usage levels.

9

AEROSOL DEGRADATION ASSESSMENTS

We look for the presence of aerosol breakdown chemicals, which are generated through heating the formulation. Our testing protocols look for a diverse range of potential degradants, in excess of what the regulators would generally require allowing for a more comprehensive evaluation of the safety of cannabis ingredients and products. By expanding the scope of analysis, we aim to provide a thorough assessment of potential risks associated with the use of cannabis ingredients and ensure the highest level of safety for consumers.



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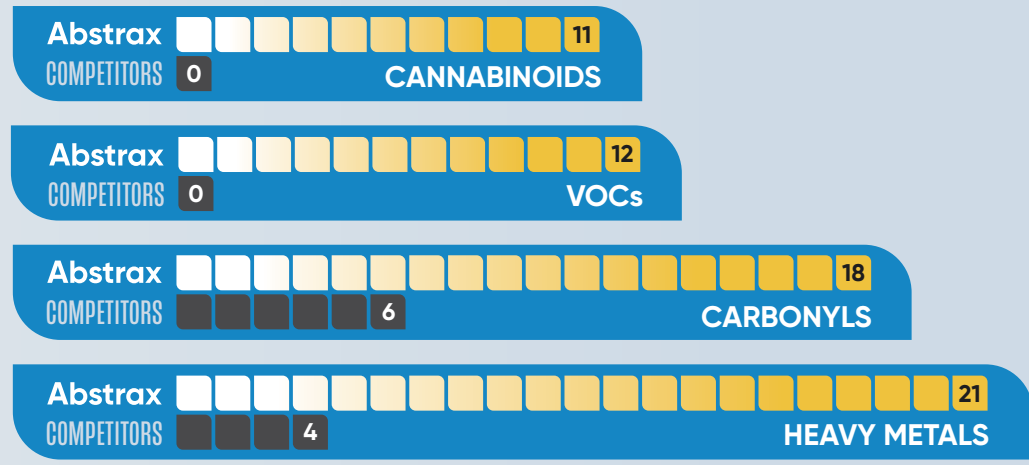
SHELF LIFE STABILITY ASSESSMENT



By conducting stability testing on your product, you can obtain valuable insights into potential issues such as the leaching of metals from the hardware or the decomposition of solutions, which could lead to the formation of new compounds throughout the product's shelf life. While the product may pass initial assessments at the production facility, it is imperative to thoroughly comprehend its long-term stability in order to satisfy regulators that a product continues to be appropriate for consumer use throughout the full duration of its shelf-life.

COMPREHENSIVE INGREDIENTS TESTING

Compare our RA-TEP to other suppliers' CMR studies



INDUSTRY-LEADING QUALITY & COMPLIANCE



Abstrax's achievement of **SQF Level 2 certification positions us at the forefront of global quality standards.** SQF is the high-water benchmark within the Global Food Safety Initiative (GFSI) that drastically outpaces the expectations set by ISO 9001:2015 or other GFSI audits like FSSC22000 that are ungraded and common amongst terpene suppliers.

It's crucial to understand that **SQF is currently held in higher global esteem** than many other

third-party audits, and here's why: unlike FSSC22000 which demands re-certification every 3 years, SQF requires it annually. Moreover, SQF provides a grading system, adding a layer of transparency that distinguishes those barely passing audit standards from those exemplifying exceptional quality practices.

Abstrax has achieved a remarkable score of 94.

THIRD-PARTY AUDITED & CERTIFIED

We operate in full alignment with 21 CFR Part 110, integrate HACCP and most notably, achieved SQF Level 2 certification, **significantly outperforming** the more typical ISO 9001:2015 and FSSC 22000 benchmarks

Abstrax is committed to providing **quality products** that customers can trust. Our team has over **50+ combined years of experience** leading safety compliance regulation for some of the world's largest flavor houses.



HACCP is the internationally recognized risk-based system for managing food safety throughout the food supply chain - from food production and preparation processes, to packaging and distribution.



The SQF program stands as one of the most esteemed Global Food Safety Initiative (GFSI) pathways and our remarkable score of 94 showcases our commitment to superior quality systems, far exceeding the norm in our industry. This is the gold standard.



GMP certification provides consumers and retailers with assurance that your product is manufactured utilizing industry best practices. Good Manufacturing Practice (GMP) is the foundation for food safety which is a prerequisite for a successful SQF audit.

WHERE INNOVATION AND SCIENCE MEETS FLAVOR MASTERY

As the **leader** in the world of botanical flavor technology, Abstrax excels in crafting innovative **terpene-driven, functional flavor solutions**. Serving the cannabis, hops, flavor and fragrance industries, Abstrax is the trusted product development partner that forward-thinking CPG brands turn to when looking for a competitive edge. Founded in California by a team of **award-winning PhD scientists, flavor chemists, and visionary product developers**, Abstrax harnesses its three divisions to craft transformative CPG applications via innovative technology and more sustainable, all natural, and cost effective ingredients.

"When you partner with Abstrax, you're choosing a company dedicated to operating with integrity, providing quality, and pursuing safety in all aspects of our operations."

Max Koby, CEO |  Abstrax.



For more information visit abstraxtech.com or reach out to us at (562) 294-5805.





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