

100 SECONDS TO MIDNIGHT?

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Are the cannabis and hemp vaping industries poised on the precipice of a catastrophe from unknown risks caused by additives, contaminants, and misbranding?

In 1947, the Bulletin of the Atomic Scientists established the Doomsday Clock, a graphical representation of the current likelihood of nuclear war, based on world events. When it was first established, the Doomsday clock was set at seven minutes to midnight, with midnight being the onset of a nuclear war. Since that time, the clock's proximity to midnight has increased and decreased. By 1991, with the decline of the Soviet Union and a new arms control treaty, the clock stood at 17 minutes to midnight. As of January, 2022, the clock is now 100 seconds to midnight – the closest we have ever been to the end of the world.

The premise of this white paper is that the cannabis and hemp vaping industries are also only 100 seconds away from midnight, while consumers and many in the industry itself appear to be completely unaware of it.

As former Secretary of Defense Donald Rumsfeld once quipped, “[r]eports that say that something hasn’t happened are always interesting to me, because as we know, there are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns—the ones we don’t know we don’t know. And if one looks throughout the history of our country and other free countries, it is the latter category that tends to be the difficult ones.”

The “known knowns” of the cannabis and hemp vaping industries are that a fairly wide variety of additives, including artificial flavors, cutting/diluent agents, and terpenes have been and apparently continue to be an integral part of the e-liquids that constitute vapes. What lurks in the dark as an unknown unknown are the long-term health risks to consumers from these products as currently formulated. Despite a wealth of information and experience from the e-cigarette industry, which has been struggling with e-liquid-focused litigation for years, the cannabis and hemp vaping industries appear to be on the cusp of a litigation reckoning of their own.

This white paper will briefly cover the legal, health, and regulatory history of the three biggest risks to the cannabis and hemp vaping industries: (1) artificial flavor additives of concern, including diacetyl, acetyl propionyl, and others, (2) other e-liquid additives like terpenes and cutting or diluent agents, and (3) misbranding and contamination.

BACKGROUND

With the piecemeal legalization of cannabis for medical and adult use in 37 states, consumers are now experiencing more than ever a wide range of products for legal cannabis consumption, including flower, tinctures, edibles, and vaping products. Even in states without some form of legalized cannabis, the legal availability of hemp-derived products such as cannabidiol (“CBD”) compliments the cannabis industry in many other states without legal access to cannabis. Many consumers prefer the experience of vaping for cannabis and hemp consumption, which has created a booming industry, projected to rise to \$37 billion by 2024.

As with any type of inhalation use, whether it be traditional smoking or vaping, consumers, manufacturers, and retailers have a natural interest in safety for their products. The e-cigarette industry has experienced litigation pressure tied, in part, to product safety for several years now. Most notable is a wave of over 2,200 lawsuits by consumers concerning Juul Labs’ nicotine vaping products, currently pending in federal court in California since 2019.

Importantly, some of the same concerns expressed by consumers and regulators in the Juul Labs litigation also have potential implications for the cannabis industry, including the use of artificial flavors previously identified by NIOSH and others as alleged health risks in settings where users can be exposed to inhalation of these flavors.

THE EXPLOSIVE GROWTH OF THE CANNABIS VAPING INDUSTRY

Over the past ten years, the United States has been flooded with headlines reporting ballot measures and state legislative actions to legalize medical and adult use cannabis. The market and technology have been quick to respond to the increase in reception and availability by offering a wide range of new products for consumers to consume cannabis.



Specifically, the practice of using vaping devices to consume cannabis or hemp-derived products has exploded in recent years, with the legalized cannabis industry reporting vaping products now account for more than 30% of their business. [i]

It is not difficult to understand the popularity of vaping given the ease of use, lack of ash, portability of the device, and access to flavored cartridges for a more enjoyable experience. However, manufacturers and product users are dismissing the red flags of the litigation history of the e-cigarette industry, citing the differences between tobacco products and cannabis products and their relative safety. Yet cannabis vaping products may have more in common with nicotine vaping products than one would imagine, as both tend to use artificial flavoring to produce various flavored cartridges. Moreover, there are other common components to vapes, whether nicotine or cannabis-based, such as cutting agents/diluents, which raise similar health concerns. While artificial flavorings have long been generally recognized as safe to flavor food products, a host of scientific literature has suggested that inhalation of some flavoring ingredients may be harmful to human lungs, and the nicotine vaping industry is now seeing a boom in litigation as a result.

NICOTINE VAPING, CANNABIS VAPING, AND THE RISKS POSED BY ARTIFICIAL FLAVORINGS

The explosion of popularity of vaping devices is not unique to the cannabis industry. Just as the number of cigarette users began to dwindle, vaping devices and e-cigarettes containing nicotine were promoted as an alternative to cigarettes, allegedly without the harmful carcinogens and other chemicals. However, over 2,200 lawsuits have arisen in multidistrict litigation involving vaping manufacturers, including JUUL Labs, Inc. (“JUUL”), alleging that vaping is arguably more harmful than cigarettes, and was marketed to teenagers and young adults as a safe alternative to cigarettes. This litigation is currently pending in the Northern District of California.

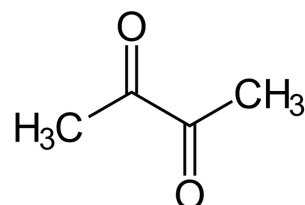
The plaintiffs allege that defendants sought to develop and market a product that would create and sustain nicotine addiction without the stigma associated with cigarettes.[ii] In doing so, plaintiffs allege manufacturers enticed newcomers with kid-friendly flavors, which were not safe for inhalation.[iii] Some of the flavors include vanilla, cool mint, cucumber, and mango. The plaintiffs cited a 2016 study analyzing the ingredients in some of the most popular vaping flavors that found the concentration of artificial flavoring in vaping fluid to be sufficiently high for inhalation exposure by vaping to be of toxicological concern, particularly with regard to the use of diacetyl, acetyl propionyl, and benzaldehyde in the vaping liquids.[iv]

Diacetyl is a four carbon α -diketone. It is one of the key components in butter flavoring that imparts a buttery taste, and has been identified as a prominent volatile organic compound.[i] Diacetyl can be either a natural or artificial flavoring ingredient.[vi]

Recent scientific literature suggests that occupational exposure to diacetyl in food production industries without the use of respiratory protection is associated with respiratory disease, including exertional dyspnea and obliterative bronchiolitis.[vii] Obliterative bronchiolitis is a rare pulmonary disease that is characterized by inflammation, narrowing, or obliteration of bronchioles in the lung.[viii] Acetyl propionyl, a five carbon α -diketone, has a similar chemical structure to that of diacetyl. As such, it also imparts a butter flavor and has been used as a supposedly safer alternative to diacetyl.

Investigation of the connection between diacetyl and obliterative bronchiolitis originally began in 1985 when NIOSH investigators first visited a microwave popcorn factory to investigate two young, previously healthy, non-smoking employees who worked in the mixing room of the factory that had been diagnosed with obliterative bronchiolitis.[ix] NIOSH noted the presence of diacetyl and other chemicals used in the factory, but could not pinpoint the cause of the employees’ sudden illness.[x] By 1993, BASF, a flavoring manufacturer, began research studies investigating the effect of diacetyl on lab rats.[v] By 1997, The Flavor and Extract Manufacturer’s Association (“FEMA”) began discussing diacetyl exposure and its impact on human respiratory health at their meetings.

In 2000, NIOSH investigators visited and inspected a Missouri microwave popcorn plant after Missouri health officials notified OSHA that ten workers from that plant had been diagnosed with obliterative bronchiolitis.[xii] After a three year study, NIOSH determined that inhalation of butter flavoring chemicals poses a serious risk for occupational lung disease.[xiii] By December 2003, NIOSH had issued a safety alert to 4,000 businesses that may have used butter flavoring suggesting safeguards and requesting the employers notify and caution workers.[xiv].



**DIACETYL
CHEMICAL
STRUCTURE**

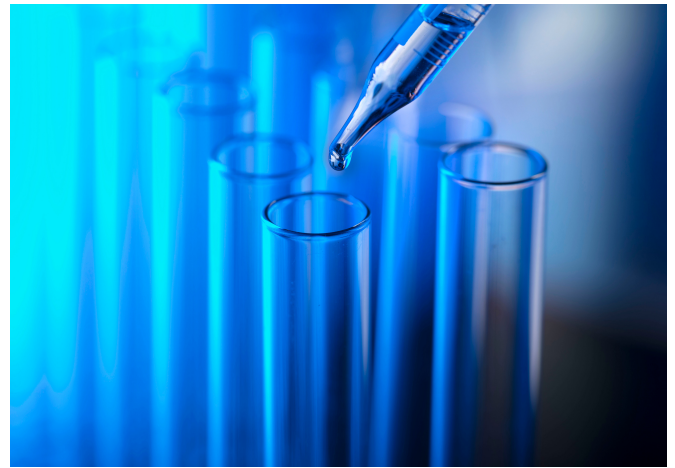
NIOSH and other private actors have continued to study the impact of diacetyl and other diketones on respiratory function. From these studies, there is some evidence suggesting that employees exposed to flavoring-related compounds can experience excessive lung function decline under certain conditions.[xv] Moreover, this risk tends to be increased where diacetyl is heated. FEMA has indicated that heating diacetyl will increase volatility and greatly increase air concentrations.[xvi]

For this reason, NIOSH recommends that during any heating processes, the temperature should be closely monitored and maintained at the lowest temperature the process can permit.[xvii] NIOSH has also developed a recommended exposure limit of 5 parts per billion (ppb) for diacetyl as a time-weighted average for up to eight hours per day during a forty hour work week.[xviii]

However, NIOSH emphasizes the importance of a short term limit, as peak exposures may have greater toxicity than the same total dose spread out over a longer period of time. [xix] NIOSH recommends a short-term exposure limit of 25 ppb for a 15 minute time period for diacetyl.[xx]

NIOSH has also issued recommended exposure limits for other diketones used in butter flavoring, including acetyl propionyl. NIOSH recommends an exposure limit below 9.3 ppb for acetyl propionyl for up to eight hours per day during a forty-hour work week. [xxi] NIOSH believes employees exposed to acetyl propionyl at this concentration would have a similar risk of decreased pulmonary function as employees exposed to diacetyl. [xxii]

In light of these concerns about diketones and inhalation risks, vaping manufacturers and retailers have taken steps to distance themselves from diacetyl and acetyl propionyl. Some have provided statements that their liquids do not contain these chemicals.



However, a 2016 study investigated the diacetyl and acetyl propionyl content in a number of sweet flavored nicotine e-liquids and discovered that many liquid vaping cartridges are exposing users to concerning levels of these chemicals. [xxiii] The study examined sweet flavored vaping liquids from European and US manufacturers including butter, toffee, milky, cream, chocolate and coffee flavors.[xxiv]

Some of the manufacturers of the liquids selected even had statements on their websites indicating that there was no diacetyl in their liquids. In fact, diacetyl was detected in 110 of the 159 samples, and acetyl propionyl was detected in 53 samples.[xxv] 52 of the samples had levels of diacetyl that exceeded the limits prescribed by NIOSH.[xxvi] Notably, diacetyl and acetyl propionyl were detected in samples coming from manufacturers that clearly stated that they were not present in their products, indicating that the chemicals were either used deliberately or were somehow present as contaminants or processing byproducts.[xxvii]

Just like nicotine e-liquids, cannabis vapes are sold in a wide variety of flavors, including fruity, candy, and herbal flavors one would not expect would require the use of diacetyl or acetyl propionyl based flavorings. Previous research has detected diacetyl, acetyl propionyl, and acetoin (a ketone) in flavored nicotine e-liquids, such as Cupcake, Fruit Squirts, Waikiki Watermelon, Cotton Candy, Tutti Frutti, Double Apple Hookah, Blue Water Punch, Oatmeal Cookie, and Alien Blood.[xxviii]

Cannabis e-liquids are also available in many similar flavors, and although there was little in the way of formal documentation of the use of diketones in cannabis e-liquids before 2022, all that is beginning to change. As reported by *Cannabis Business Times*, in February, 2022, the State of Pennsylvania issued a mandatory recall of hundreds of cannabis vaping products.[xxix]

After an apparently months-long review by state regulators, the state Department of Health issued a recall memorandum on February 2, 2022, finding that “the Department has determined that certain vaporized medical cannabis products containing some added ingredients have not been approved for inhalation by the United States Food and Drug Administration (FDA).[.] Although some of these added ingredients may be considered safe in other non-inhaled products, patient safety is the top priority of the Medical Cannabis Program. Therefore, the Department has issued a mandatory recall for all affected vaporized products.”

The recall list included a five-page spreadsheet of hundreds of added ingredients found in the cannabis vaping products, none of which has been approved by the FDA for inhalation use.[xxx] It is not clear what all of the added ingredients were used for, but many of them are obviously food flavorings, including a diketone, 2,3 hexanedione (acetyl butyryl), that may pose an inhalation risk similar to diacetyl. Acetyl butyryl is sometimes used as a replacement for diacetyl in food flavorings, and has a creamy, caramel flavor.[xxxi] Although it has not been rigorously studied, NIOSH has suggested that acetyl butyryl may pose similar inhalation risks to diacetyl and acetyl propionyl, because it is also an α -diketone in the same class of chemicals.[xxxii]

As a result of the research linking diacetyl and other diketones to lung disease, both the FDA and FEMA have issued guidance stating that use of artificial flavors in vaping products should be rigorously studied for safety before they are used in e-liquids.

Despite this guidance and growing concerns about artificial flavors in the industry, it is a normal practice for manufacturers and retailers to sell vaping liquids and cartridges without a full ingredient list. In fact, as discussed above, the research indicates that even where manufacturers have advertised the lack of diacetyl in their liquids, it is still detected in their samples.

At this juncture, there is no way to know whether these misleading statements are intentional or if diacetyl and other diketones are created as a processing byproduct of which they were unaware. In any event, it stands to reason that even consumers who receive assurances from manufacturers that a vaping product does not contain diacetyl cannot be sure that they are not inhaling it nevertheless.

VITAMIN E-ACETATE AND OTHER E-LIQUID CUTTING AGENTS

In addition to newly-emerging hard evidence of the use of artificial food flavorings in cannabis e-liquids, yet another litigation risk on the horizon relates to other additives in e-liquids, including cutting agents or diluents that have raised concerns in the past, such as vitamin-E acetate, squalene, and squalane. Vitamin-E acetate historically has been used as a thinning or “cutting” agent by e-liquid manufacturers due to its ability to both dilute and thicken THC oil. Both of these qualities theoretically make it an ideal ingredient for cannabis e-liquids.[xxxiii]

In practice, however, experience has shown that these additives are anything but safe for inhalation. In 2019, the United States experienced a rash of serious lung injuries attributed in part to the use of vitamin-E acetate in counterfeit cannabis vapes. This series of injuries is thought to have killed one consumer in Illinois, and injured 215 people in 25 states.[xxxiv] Many consumers and industry watchers have likely assumed that this was a one-time event, and let serious questions remain about what cutting agents other than vitamin-E acetate might still be used in the legal cannabis market.

For instance, in December, 2020, the State of Oregon identified two other cutting agents, squalene and squalane as “adulterants,” and moved to prohibit their use in regulated cannabis products in that state.[xxxv] As the Oregon Liquor Control Commission explained, these cutting agents constitute a particular concern, because they degrade into other chemicals when vaporized at high temperatures, including, acetone, methanol, acetic acid, and formic acid.[xxxvi]

What the State of Pennsylvania’s vaping cartridge recall shows is that squalene is still being used as a cutting agent, despite over a year and half of regulatory interest in eliminating this additive in the industry – one or more of the products recalled were identified to contain squalene.[xxxvii] The ultimate fallout from the state’s action is unclear, but in the short term the recall has spurred two industry lawsuits against the state.

A trade group and one vape manufacturer have challenged the state’s authority to issue the recall, and have sought the return of embargoed merchandise, estimated to be worth nearly \$18 million.[xxxviii]



MISBRANDED VAPING PRODUCTS

As previously noted, although only 37 states have some form of legalized cannabis, in the majority of the remaining states, some form of hemp-derived products like CBD is available to consumers as an alternative. One of the most controversial of these products is Delta-8 THC. Delta-8 THC is an isomer of Delta-9 THC (the main psychoactive chemical in cannabis). In other words, both Delta-8 and Delta-9 have the same chemical formula, differing only on the location of one chemical bond. Delta-8 can be derived from hemp via a chemical extraction and refinement process, and then manufactured into an e-liquid, just like a Delta-9 cannabis vape. Delta-8 products have been marketed as a “legal high” in states without legal adult-use cannabis. They have also been touted as a “THC lite” experience, for consumers preferring a less intense high compared with cannabis products. The legality (or lack thereof) of Delta-8 continues to be a point of significant controversy.

Even setting this debate aside, however, another issue creating waves recently is the reporting of several studies showing that numerous Delta-8 products on the market are misbranded, containing surprising and clearly illegal levels of Delta-9 THC, in addition to other contaminants.

The U.S. Cannabis Council, a cannabis trade organization, analyzed 16 Delta-8 vaping products for levels of contaminants, including Delta-9.[xxxix] The analysis was shocking – not only were 25% of the products positive for heavy metal contaminants, 15 of the 16 products also contained illegal levels of Delta-9.

Additional studies of Delta-8 products have produced consistently similar results. In late 2021, the trade journal Leafreport published an analysis of 38 Delta-8 products, finding numerous inaccuracies with the products’ descriptions.[xl]

The sampling covered a wide variety of Delta-8 products, including vapes, tinctures, and gummies.[xli] Of the products sampled, 68% contained a significantly different concentration of Delta-8 than reported on the label.[xlii] One of the products, a Delta-8 vape, even contained a whopping 15.2% Delta-9 concentration. [xliii]

Another analytical study of 51 Delta-8 products reported by CBD Oracle showed similar results.[xliv] This study also included a sampling of a variety of product lines, including flower, edibles, pre-rolls, tinctures, and vaping products.[xlv] In this study, an even more sizeable majority (76%) of the products contained illegal Delta-9 levels.[xlvi] One product, a disposable vape pen, contained a 23.17% concentration of Delta-9.

Trends in the studies suggest that Delta-8 vaping products are more likely to be misbranded than other types of Delta-8 products. In the Leafreport study, edible products such as gummies that exceeded the Delta-9 threshold tended to still contain less than 5% Delta-9.[xlvii] In contrast, vaping products consistently contained the highest concentrations of Delta-9 (i.e. 10-15%). Similarly, in the CBD Oracle study, vaping products consistently contained higher Delta-9 levels compared to flower, tinctures, and edibles.[xlviii]

Delta-9 contamination of Delta-8 vaping products is just one misbranding issue facing the hemp market. A recent study of 27 Delta-8 vaping products revealed widespread issues with contaminants and inaccurate COAs from the manufacturer. The study, performed by the University of Rochester, found that none of the tested products had an accurate description of its Delta-8 concentration, and 11 of the tested products contained unwanted byproducts of Delta-8 synthesis, including heavy metals, such as mercury and lead.[xlix]

As these various studies show, there is little doubt that e-liquid contamination in Delta-8 is probably a widespread problem. Commentators have posited several potential explanations regarding why so many apparently misbranded Delta-8 products exist. Delta-8 extraction problems form the first potential source of contamination. Delta-8 production from hemp requires solvent extraction, conversion of CBD to Delta-8 with a reagent, and then distillation and purification.[i] A significant amount of Delta-9 is made during this process as well, and failing to adequately distill the final product can potentially lead to unintentionally high Delta-9 levels.[ii]

Another explanation focuses on faulty laboratory analysis as the culprit. Because Delta-9 and Delta-8 are so similar, they can be very difficult to separate analytically in labs, either internally at a Delta-8 processor, or externally when obtaining a certificate of analysis (“COA”) before marketing a Delta-8 product.[iii] This is partially due to a lack of an industry-standard analytical process for solvent selection/technique during manufacturing or post-manufacturing analysis, which can spike the detected amount of Delta-9 in a sample, thus skewing results upward.

On the opposite side, it is also possible for a less-specialized analytical chemist to mistakenly report Delta-9 detected in a sample as Delta-8, due to the similarity of their respective signals in a chemical separation test.[iiii] This results in under inclusive Delta-9 sample results.

Yet another possible explanation is potentially due to Delta-8 chemical degradation after Delta-8 products have been packaged for sale.[liv] Delta-8 is not as stable an isomer as Delta-9, and in fact can degrade into Delta-9 over time and under certain conditions.[lv]



Finally, most concerning is documented evidence of what appears to be intentional misbranding by some Delta-8 processors.

The CBD Oracle study found through interviews and other investigation that a significant minority (10%) of COAs for the products were falsified or altered. Similar apparently intentional falsification of COAs was documented by Longman, where multiple labs confirmed that COAs for products purportedly analyzed by those labs were actually altered, older COAs.

Misbranding issues are not solely the issue of the hemp industry. There have been multiple reports of misbranding in the cannabis vaping industry as well. Recently, the Oregon company Cura agreed to pay a \$110,000 fine to the State of Oregon, related to its alleged misbranding of its vapes as only containing “cannabis distillate” and “cannabis” terpenes. [lvi] Instead, Oregon regulators discovered that Cura’s vaping products contained botanical terpenes, a flavoring ingredient not made from cannabis, and a multi-chain triglyceride (“MCT”) thinning oil in the products as a cutting agent/diluent.[lvii]

Although not extensively studied, early research suggests that MCT may present an inhalation risk when it is heated and aerosolized.[lviii] In addition to the hefty fine paid to regulators, Cura also agreed to pay \$500,000 to settle class action claims brought by consumers related to the disclosure.

RISK MANAGEMENT SOLUTIONS

As more users turn to vaping as their preferred method of cannabis or hemp consumption, the litigation risks highlighted in this white paper are only going to become more pressing on the industry.

All levels of the cannabis and hemp industries should carefully consider risk management policies in light of the potential for industry-wide litigation.

Cannabis and hemp growers will need to ensure their contracts with industry purchasers include indemnity agreements to hold them harmless should litigation arise. Of course, cannabis and CBD themselves are not the components of vaping products that raise safety concerns. And while there is a component parts doctrine that serves as a complete defense at trial to shield suppliers of raw materials, this defense alone will not protect growers, processors, or e-liquid manufacturers from being sued in the first place.

E-liquid processors and manufacturers will need to include indemnity agreements in their contracts as well. Moreover, they should contractually require all flavor manufacturers with whom they contract to certify that their products do not contain any chemicals not approved by the FDA for inhalation use. As is increasingly clear by the scientific literature, even these assurances may not prevent the presence of these chemicals.

As such, a prudent processor or manufacturer should carefully vet COAs from any component part supplier, and potentially consider having independent analysis performed to verify component part purity.



Moreover, widespread issues with COA accuracy from various products also suggests that the industry as a whole should establish best practices in the use of analytical chemistry, as well as development of standardized extraction processes that avoid the use of potentially dangerous and contaminating solvents.

Finally, the insurance industry is and will continue to take steps to mitigate its potential risks. One strategy that is becoming prevalent after the vitamin-E acetate episode of 2019 is the use of specified products exclusions in policies, specifically naming any potential additive of concern that would exclude policy coverage. Other policies will exclude vaping products altogether from bodily injury coverage.



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