

The full ASTM Technical Paper can be found here.

Delta-8-THC is a synthetically created psychotropic cannabinoid converted from hemp-derived CBD found in legal hemp and added to a variety of products that are sold. There is little to no regulatory oversight in the delta-8 industry and is one of many synthetically derived cannabinoids of concern.  $\Delta 8$ -THC is an isomer of  $\Delta 9$ -THC, the most common cannabinoid that produces psychoactive effects, and is categorized as a Schedule I drug under the United States Controlled Substance Act. The only difference between  $\Delta 8$ -THC and  $\Delta 9$ -THC from a physical perspective is the location of the double bond between two carbons.  $\Delta 8$ -THC is also a moderately psychoactive cannabinoid, producing similar but milder effects than  $\Delta 9$ -THC.

Natural delta-8 THC is not economically feasible to extract, but in 2001, a method was patented to convert CBD into delta-8-THC utilizing solvents as a catalyst, including harsh and toxic chemicals, which creates many impurities that are not well characterized. The result is an impure oil that needs further clean-up to minimize the byproducts to an acceptable level. This process differs from the extraction and isolation of CBD and delta-9-THC from the cannabis plant in that it involves significantly more advanced chemistry. "The level of complexity is more akin to the creation of active pharmaceutical ingredients (or APIs) which for good reason, requires appropriate characterization of toxicological and safety risks, and extensive data collection during the development of the process to sufficiently validate. This includes the adherence to federally and internationally recognized Good Manufacturing Practices (or GMPs) to which very few if any producers in the marketplace have demonstrated their ability to conform."

In one study, over 50% of  $\Delta 8$ -THC products contained illegal (over 0.3%) quantities of the psychoactive  $\Delta 9$ -THC compound, and 68% contained the wrong amount of Delta-8. The study "confirmed that Delta-8 products are mostly offered by inexperienced companies looking to make a quick buck."

The emergence of  $\Delta 8$ -THC in the hemp-based products marketplace has created a false public perception that the products are safe. These products are often sold in gas stations, convenience stores, and even some cannabis dispensaries. Marketing ploys have described  $\Delta 8$ -THC as being a safe and legal alternative to  $\Delta 9$ -THC and have aligned it with the CBD and wellness camp. The less publicized reality is that use can result in failed drug tests, which can jeopardize careers, child custody battles, etc. Additionally, there are existing reports from poison control centers showing hospitalizations that have been directly linked to consuming  $\Delta 8$ -THC products as well as reports of amateur producers obtaining battery acid and pool chemicals to create products that they advertise as delta-8. Respiratory events were the most commonly reported adverse event using the FDA adverse event reporting system (FAERS) in cases listing  $\Delta 8$ -THC as the suspect drug.

Simply banning delta-8-THC does nothing to address the next wave of synthetic cannabinoids. To minimize the risk of impurities that can further impact consumer health, safety and performance

standards are necessary. Common sense solutions exist in already established frameworks (such as the Pure Food and Drug Act) to proactively address how to ensure products are evaluated and regulated to keep consumers safe without adversely impacting businesses and the global supply chain. As well as regulation, defining how to label products that contain potentially intoxicating cannabinoids and a systematic reporting process of adverse events would be beneficial.

The United States Pharmacopeia, working in tandem with ASTM International, also debuted a USP technical white paper, on delta-8-THC, which can be found <a href="https://example.com/here.">https://example.com/here.</a>