Purity Matters
Distillate vs. High Purity Delta 9 THC

11 January 2023

By Aimee O'Driscoll: Aimee is a freelance science writer with over a decade of experience as a development chemist. She has written about the cannabis industry since 2020 for publications including Analytical Cannabis, Lab Manager, and Leafly.

The global cannabis industry continues to evolve rapidly with legalization in a growing number of regions increasing overall demand for high quality THC-infused consumer products. As this market grows and matures, expectations are that large Consumer Packaged Goods (CPG) manufacturers will undertake large-scale investments to produce, market and distribute these products. Arguably, the gating issue for global CPGs to fully commit their brands to this market is the quality, consistency and purity of the THC infusion ingredients that must conform to strict food-grade standards and Good Manufacturing Practices (GMP).

Presently, cannabis products are typically infused with distilled THC extracts. The distillation process refines crude THC oil using heat in an attempt to separate the active ingredient from other undesirable ingredients. However, distillate-based THC purity levels in most consumer products currently top out between 90-93% with 7-10% impurities. In addition to the impurities, we also know that as a consequence of the distillation process, undesired artifacts and isomers of

desired Δ9-THC (including Δ8-THC) are created, which ultimately impact product quality, consistency, taste, user experience, safety and other factors.

CPG-quality infusion ingredients leverage advances in chemistry and technology to overcome these problems, utilizing production methods that forgo distillation entirely and yield API-quality ingredients with far greater purity, consistency and quality. For example, Protonify's non-distilled, botanically-derived THC and THCa isolates offer cannabinoid purity levels approaching 100%.

Here, we explore the challenges associated with cannabis distillates and examine how companies are using pure ingredients to manufacture higher-quality, safer products with consistent user experiences that global CPG brands can efficiently and effectively utilize in their supply chains.

Formulating with distillates has inherent challenges

Distillation has long offered a convenient method to extract desired cannabinoids, specifically Δ9-THC, the infusion ingredient found in most of the current Cannabis 2.0 retail products. While deemed adequate for today's recreational products, the health effects of the impurities and artifacts created by various distillation processes have not been extensively examined, especially in the context of the quality standards typical of CPG brands.

The first inherent challenge with distillate-based THC, is a lack of uniform operating procedures for the extraction and distillation processes. Different processes result in different byproducts. For example, it is suspected that the acidic or basic nature of various filtration media may be responsible for byproduct formation. The bottom line is that THC infusion material created via distillation can vary significantly from batch-to-batch and from one distillation process to another, resulting in unpredictable impurity profiles.

Multiple studies also show that distillation introduces at least three isomers of Δ9-THC including Δ10-THC, Δ8-THC and Δ6a,10a-THC. Each of these isomers introduces potential issues with toxicity, taste and overall user experience. For instance, according to the WHO Expert Committee on Drug Dependence Pre-Review, "Stereoisomers of Δ10-THC "have not been assessed in any detail for their toxicity". Lack of available information is concerning, considering that meaningful amounts of Δ10-THC can typically be found in THC distillate.

As well, according to the U.S. Food & Drug Administration (FDA), Δ8-THC can pose serious health risks and products containing Δ8-THC have not been approved. Note also that Δ8-THC is not naturally resident on the plant and is instead a byproduct of processing. Both Δ8-THC and Δ10-THC are also known to be significantly weaker agonists at the CB1 receptor in our body's endocannabinoid system compared to Δ9-THC, adding to uncertainty of user experience.

Most recently in Canada, the Ontario Cannabis Store will no longer be listing Δ8-THC products until it receives guidance from Health Canada, noting that products that contain Δ8-THC fall

"outside the definition of THC under the federal Cannabis Act". In their letter, the OCS says they have been monitoring "emerging concerns in the United States, where the Food & Drug Administration (FDA) has issued public health warnings for unregulated products that contain the novel synthetic cannabinoid Δ8-THC. As a result, an increasing number of U.S. States have taken steps to regulate or ban products that contain this cannabinoid."

Another isomer, Δ6a,10a-THC, is also not a naturally occurring cannabinoid and is generally created by chemical synthesis as part of the distillation process.

Aside from these impurities diluting the levels of desired Δ9-THC, their toxicity, potency and effects are not well-studied, so the short and long-term health impacts are unknown.

It is also well known that artifacts produced during the distillation process introduce negative taste issues for products including beverages and edibles, which prompt many manufacturers to compensate with flavors, sugars and other additives. Adding "artificial" components to cannabis products can negatively impact user perception of the brand.

Other impurities identified include azulenes, a contaminant that is linked to the presence of THC isomers, residual solvents, pesticides, microbes, heavy metals, and phthalates, many of which become concentrated during the extraction process. While testing methods are in place to detect these components, they are not always reliable and can vary across testing labs. Further, even if levels test below thresholds, there is evidence that solvents create taste issues. Indeed, it's common for products to be recalled due to many of these issues. And understandably, the presence of contaminants in extracts also limits their pharmacological use.

Distillation technology used to manufacture THC infusion material has been available for several decades and advances have been made that have adequately supported recreational products available in today's legal market. However, distillation technology has limitations that arguably prevent the wide-scale proliferation of large global CPG consumer products. Fortunately, another pathway to a purer, more consistent form of THC exists.

Pure THC Overcomes these Challenges

Increasingly discerning consumers are demanding contaminant-free products that feature high purity and are seeking more predictable, "clean" experiences accurate to the label on the product. As such, producing a purer, more consistent form of Δ9-THC without impurities has become critical for the industry to progress. Fortunately, pathways to pure THC exist that do not utilize distillation and that produce API-quality THC infusion material.

Protonify Corporation creates pure Δ9-THC using a different pathway - without distillation - by starting with ultra-pure THCa which is then decarboxylated to produce Δ9-THC. By isolating THCa to purity levels approaching 100% using organic chemistry, all impurities are removed prior to decarboxylation with the resulting Δ9-THC material being 98%+ pure and the remainder being

only minor cannabinoids without any impurities. A further advantage of Protonify's unique pathway to Pure THC, is the ability to tune the inputs to refine the output. Distillation removes impurities after the fact. They are stuck with whatever the biomass gives them in their first push. Protonify technology enables specific tuning of the manufacturing efficiency and yield in real time removing any unwanted material as and when it is discovered at the lowest cost point of removal.

With a scalable manufacturing process that adheres to GMP standards, large CPG companies are already utilizing Protonify's pure THC in their formulations to address the issues around taste and product inconsistency characteristic of distillate-based oils. Pure ingredients are inherently stable and easy to handle, making them ideal for formulating a range of product types, including beverages, edibles, and infused pre-rolls.

Formulating with Pure Cannabinoid Ingredients

There are many advantages to utilizing high-purity cannabis ingredients and from the manufacturer's perspective, it essentially comes down to reducing complexity and risk and increasing consistency. Starting with high-purity materials, reduces multiple friction points in the manufacturing process. For example, it negates the need for fillers and additives that might impact costs and taste and negatively impact the user experience. From a consumer perspective, they are enjoying a cleaner, more consistent product that doesn't come with impurities that introduce a host of potential health risks.

Pure cannabinoid ingredients present product formulators with a unique set of pure, CPG-grade infusion materials to offer new, differentiated product SKUs including:

Liquid Diamond Vapes: Gaining in popularity in markets such as California, liquid diamond vapes provide the cleanest, strongest, most consistent vape experience on the market. Products are formulated with THCa isolate decarbed into the purest THC infusion material available, with purity approaching 100% total cannabinoids, including 98%+ THC. The result is a vape with only Δ9-THC and terpenes: no other impurities. Manufacturers can also choose to add CBD or other inputs for virtually limitless, unique SKU possibilities and brand differentiation.

Beverages and Edibles: Distillate-based beverages and edibles typically require extra ingredients to mask the taste of cannabis, which adds steps to the formulation process. Pure Δ9-THC made from THCa isolate requires no additives to hide taste. In addition, onset times are typically faster and more consistent. Most importantly, edibles made from pure Δ9-THC are free from distillation-based impurities that create many negative side-effects both during and post-experience.

Any extract combination in a "Diamond-infused" pre-roll: Any extract (for example, hash, live resin, rosin, or shatter) can be infused with Protonify's THCa isolate powder to achieve higher potency without adding impurities. Product formulators can create unique SKUs, providing a marketing differentiator, by adding THCa isolate - different from THCa Diamonds that contain

impurities. Adding THCa to extracts also allows producers to enhance any flower, including potentially lower potency material.

Soft gels, tinctures, and tablets: For consumers who prefer to consume cannabis without inhalation, soft gels, tinctures, sublingual strips, and tablets present attractive options. Pure cannabinoid formulations are the fastest-acting cannabis products available with no odor or taste. Doses are easy to fine-tune, making them a great choice for beginners building formulations using cannabinoid APIs. This allows producers to formulate high-purity, pharmaceutical-grade products with the quality and consistency required for their production processes.

Infused flowers with THCa: THCa isolates approaching 100% purity are manufactured to a particle size much smaller than icing sugar. When infused in biomass, THCa isolate homogenizes perfectly, resulting in a milled flower ready to package or roll. The high purity levels of THCa isolate means zero residual solvents and therefore no alteration of the original terpene or minor cannabinoid profile of the flower—simply add pure molecules to achieve a higher potency.

Protonify Corporation is a privately-held Canadian licensed global B2B manufacturer of highest-purity, CPG-grade cannabinoid isolates. Protonify's botanically-sourced cannabinoids are non-synthetic with purity approaching 100%. Available in several formats, including dry powder and nano-encapsulated, they fit seamlessly into traditional CPG formulation recipes, industrial scale production lines and supply chains; and are the perfect foundation to enable cannabis product formulators and manufacturers, to safely and reliably build brand affinity for consumer packaged goods containing THC and THCa. Manufacturing of Protonify ingredients strictly follow Good Manufacturing Practices (GMP) for extracted products, aligning with existing GMP / ISO / HACCP standards and are the foundation for the next generation of Cannabis 3.0 high purity products including Infused pre-rolls, beverages, vapes, edibles, sublingual strips and tablets.

https://www.protonify.com
info@protonify.com
+1(647)-360-8422

Protonify Corporation
1451 Island Highway East
Nanoose Bay
British Columbia
Canada, V9P 9A3