Delta-8-THC

REGULATORY ISSUES PRESENTED BY ARTIFICIALLY-DERIVED CANNABINOIDS

What is Δ^8 -THC?

Delta-8-THC (Δ^8 -THC, sometimes just called "Delta 8" or "D8") is an intoxicating cannabinoid. Users reports effects very similar to Delta-9-THC (Δ^9 -THC), but less potent.

Delta-8-THC has been reported to be naturally occurring in cannabis in <u>very low</u> concentrations, typically less than 0.1%. The majority of Δ^8 -THC on the market is artificially created from CBD.

Delta-8-THC has a very similar chemical structure to Δ^9 -THC:



How Δ^8 -THC is made

Delta-8-THC is most commonly made from CBD.

CBD is extracted from cannabis. The extracted CBD is mixed with an acidic catalyst and for a period of time. This process converts much of the CBD to Δ^8 -THC via "isomerization."

This process produces known and unknown byproducts.

It is unclear whether, or to what extent, the Δ -THC manufacturers attempt to purify the product to remove the byproducts or the catalyst.

It is common to see Certificates of Analysis for Δ^8 -THC between 70% and 85%, with the other 15% to 30% being "unknowns."

- Typical cannabis extracts have some "unknowns," but these are substances that naturally occur in cannabis such as waxes, plant matter, and terpenes.
- Delta-8-THC is typically made from high-purity CBD isolate, often upwards of 99% purity. When the starting material is that pure, it means that any "unknowns" in the resulting mixture of chemicals are reaction byproducts rather than substances that were extracted from cannabis.

Why Δ^8 -THC is important

Many hemp-derived Δ^8 -THC products are completely legal commodities in Oregon. Outside the OLCC market, these products are subject to very little regulation and may be sold by anyone, including to minors.

Delta-8-THC is not contemplated in statute.

The Testing for Δ^8 -THC is not required.

Delta-8-THC is not included in OHA marijuana concentration limits. An OLCC Processor is limited to 50 mg Δ^9 -THC in an edible but could add an unlimited amount of Δ^8 -THC to an edible.

There is relatively little history of humans consuming higher concentrations of Δ^8 -THC.

It is also unclear whether there are long- or short-term health effects from consuming the byproducts and impurities created through the manufacture of Δ^8 -THC.

Consumer understanding of these products is incredibly limited, so it is difficult for many consumers to make informed decisions about consuming Δ^8 -THC. This is exacerbated by marketing.

Why Δ^8 -THC is important

Google Trends: Interest over time for "delta 8" web searches:



July 6, 2020: <u>New Legal THC Product Is Costing Dispensaries Billions</u>. LA Weekly.

August 4, 2020: <u>Delta-8 THC Now Available From Coast To Coast</u>. High Times.

February 27, 2021: What Is Delta-8-THC?: The Hemp Derivative That's a Hot Seller. NY Times.

OLCC Labeling Requirements



In the OLCC marketplace, Δ^8 -THC products are primarily labeled as "hemp items" because the vast majority of the CBD used in the isomerization process comes from hemp.

OLCC's labeling rules do not contemplate labeling products with Δ^8 -THC or other artificially derived cannabinoids. This is because when the rules were written, experimentation with these substances was not yet widespread.

Only Δ^9 -THC and CBD are required to be listed on a label. Δ^8 -THC and other artificially-derived cannabinoids are not required by rule to be listed on a label. This creates a public safety risk because consumers may become more intoxicated then they anticipated. Additionally, they may not fully comprehend what they are consuming.

The public likely assumes that cannabis products with Δ^8 -THC or other artificially derived cannabinoids are all "natural" – that is the cannabinoids are extracted directly from the cannabis plant itself and are not the results of chemical conversion process.

Testing Examples: Unknowns

Analyte	LOQ	Mass	Mass
	mg/g	mg/g	%
THCa	0.4	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
∆9-THC	0.4	11.7	1.17
∆8-THC	0.4	543.7	54.37
THCVa	0.4	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
THCV	0.4	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
CBDa	0.4	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
CBD	0.4	0.9	0.09
CBDVa	0.4	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
CBDV	0.4	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
CBN	0.4	4.3	0.43
CBGa	0.4	0.6	0.06
CBG	0.4	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
CBCa	0.4	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
CBC	0.4	2.2	0.22
CBLa	0.4	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
CBT	0.4	3.3	0.33
∆10-THC	0.4	4.2	0.42
Exo-THC	0.4	<loq< td=""><td><loq< td=""></loq<></td></loq<>	<loq< td=""></loq<>
Total		570.7	57.07

This certificate of analysis (COA) is from a Δ^8 -THC hemp extract. Total Δ^8 -THC is 54% Total Δ^9 -THC is 1% Total CBD is less than a percent The total cannabinoids detected are 57% The other 43% is of an **unknown composition**. Typical cannabis extracts do have some "unknowns" that are not required

to be tested for. But these are substances that naturally occur in cannabis such as waxes, plant matter, and terpenes. However, a 43% unknown composition is **well outside the norm.**

Testing Examples: Circumventing Concentration Limits

Cannabinoids	mg/g	LOQ
ТНСА	<loq< td=""><td>0.0590</td></loq<>	0.0590
delta 9-THC	0.133	0.0590
delta 8-THC	4.24	0.0590
CBGA	<loq< td=""><td>0.0590</td></loq<>	0.0590
CBDA	<loq< td=""><td>0.0590</td></loq<>	0.0590
CBD	<loq< td=""><td>0.0590</td></loq<>	0.0590
CBN	0.0933	0.0590
CBG	<loq< td=""><td>0.0590</td></loq<>	0.0590
СВС	<loq< td=""><td>0.0590</td></loq<>	0.0590
Total CBG	<loq< td=""><td>0.0590</td></loq<>	0.0590
Total Cannabinoids	4.46	0.0590

This COA is from a 60 gram edible containing ten servings.

Total Δ^{8} -THC in the package is **254 mg**

Total Δ^9 -THC in the package is **8 mg**

If this product were a hemp edible, it would be **legal to sell in the general marketplace.** Note the recreational concentration limit set by the Oregon Health Authority for marijuana edibles is 50 mg of Δ^9 -THC in the package and 5 mg per serving.

In the OLCC-regulated marijuana market

OLCC rules only apply to our regulated adult use market.

Under current OLCC rules, these products are prohibited:

45-025-3220 General Processor Requirements

(3) A processor may not treat or otherwise adulterate a cannabinoid product, concentrate or extract with any additive or substance that would increase potency, toxicity or addictive potential, or that would create an unsafe combination with other psychoactive substances. Prohibited additives or substances include but are not limited to nicotine, caffeine, polyethylene glycol, or any chemicals that increase carcinogenicity or cardiac effects.

Treating CBD with a catalyst to convert it to THC increases the potency, so it is prohibited under OAR <u>845-025-3220</u>(3). Adding Δ^8 -THC to a marijuana item also increases the potency, so it also violates this rule.

In the OLCC-regulated marijuana market

Regarding hemp-derived Δ^8 -THC in the OLCC system:

Under OAR <u>845-025-2785</u>(7), all requirements for marijuana items also apply to hemp items within the OLCC system. This means OAR <u>845-025-3220</u>(3) applies to the isomerization of hemp-derived CBD and the use of Δ^8 -THC in hemp items as well.

Under OAR <u>845-025-2755(3)(a)(C)</u>, a hemp handler with an OLCC hemp certificate can only transfer hemp items that comply with the requirements for marijuana items under OLCC's rules. Because the isomerization of CBD to THC and the addition of Δ^8 -THC is prohibited under OAR <u>845-025-3220(3)</u>, isomerized Δ^8 -THC and hemp items containing Δ^8 -THC cannot be transferred to OLCC licensees.

In the OLCC-regulated marijuana market

There are some products containing Δ^8 -THC already on shelves at OLCC-licensed Retailers.

These products had labels approved before OLCC had considered the full scope of this issue and determined that Δ^8 -THC products are effectively prohibited under our rules.

At this time, our staff are not taking compliance action on products that had <u>previously</u> <u>approved</u> labels.

One of the subjects staff would like to explore in rulemaking is how those products should be handled.

Other artificially-derived cannabinoids

 Δ^8 -THC is not the only isomer of THC. And isomers are not the only artificial cannabis derivatives that businesses may be interested in manufacturing.

Some of the artificially-derived cannabinoids occur naturally in cannabis. E.g.:

- Δ⁸-THC
- Δ⁹-THC
- CBN (cannabinol)

Other artificially-derived cannabinoids do not occur naturally in cannabis but can be made via isomerization or synthesis from chemicals that occur in cannabis. E.g.:

- Δ^{10} -THC
- THC acetate esters: Δ^9 -THC-O-acetate is reported to be about three times more potent than Δ^9 -THC
- Etc.

Next Steps

Staff is asking that you initiate rulemaking to address Δ⁸-THC and other artificially-derived cannabinoids. We do not have any proposed rule language yet, but are looking forward to exploring a variety of possible approaches with stakeholders.

Our rulemaking is not able address the broader issue of untaxed intoxicating hemp cannabinoid products in the general marketplace that can legally be sold to minors.

We have begun meeting with our partners at the Oregon Department of Agriculture and Oregon Health Authority to discuss these issues.

Oregon legislators are beginning to take a look at these issues. Legislation may help to guide our approach in rulemaking and clarify OLCC's authority to regulate these substances within Oregon's adult use marketplace. We anticipate this issue being discussed at a legislative public hearing on HB 3000 next week.