

## Workshop on Cannabis Product Quality

# Analytical Testing for the Cannabis Industry: Consumer Safety vs Regulatory Requirements



**December 8<sup>th</sup>, 2022**

**Christopher J. Hudalla, Ph. D.**  
**Founder/Chief Scientific Officer**  
**ProVerde Laboratories, Inc.**

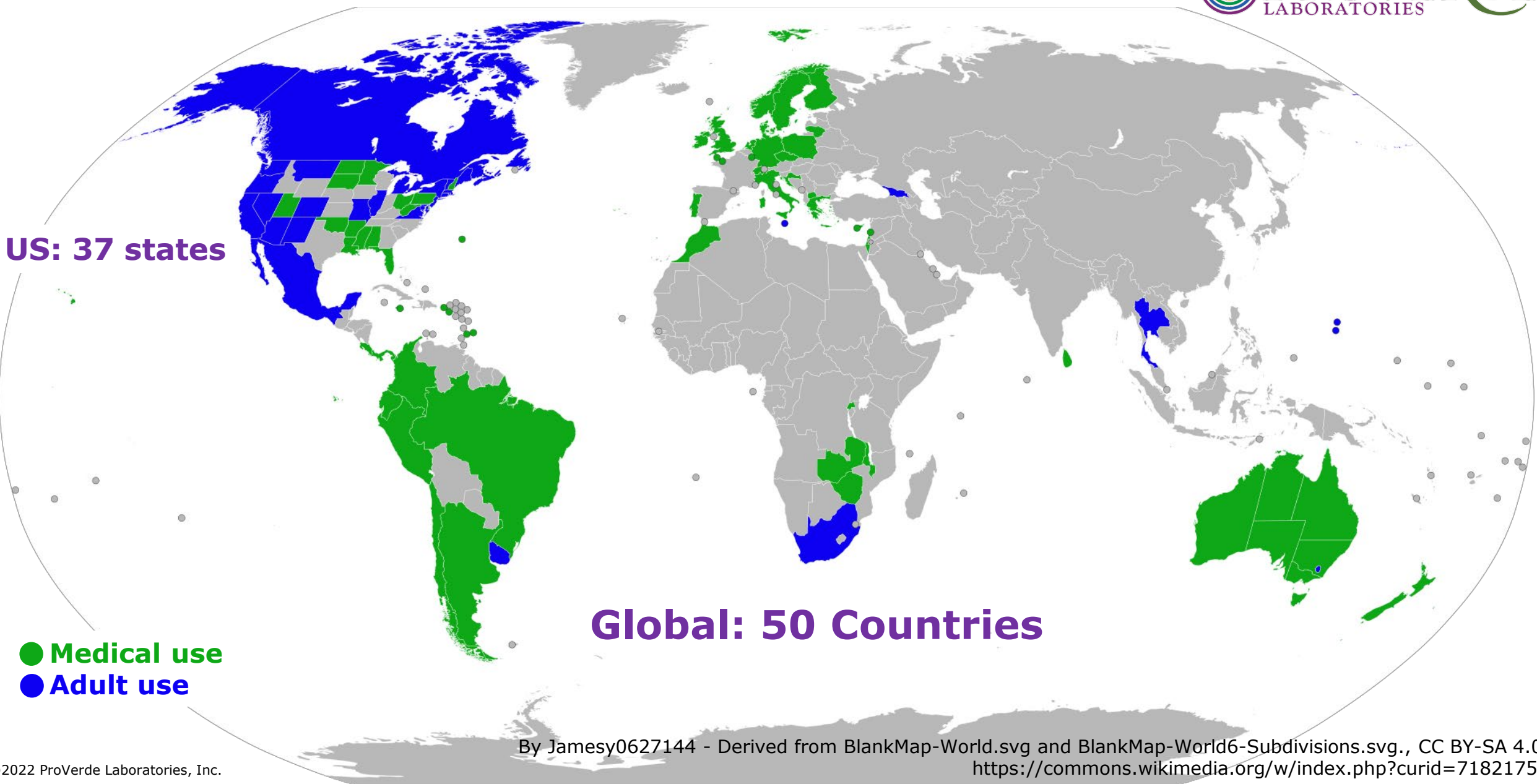


# Outline

- Increasing global acceptance for cannabis
  - Multiple regulatory jurisdictions (Country, State, Municipality)
  - Quality requirements vary greatly
- Regulations, contaminants, action limits and testing methods
  - Product sampling for laboratory submission
  - Cannabinoid potency
  - Pesticide testing
  - Microbial testing
  - Lack of harmonization (standardized methods or processes)
- Economic pressures on regulated market
  - Black market
  - Synthetic cannabinoids and analogs



# Global Acceptance – Cannabis Regulatory Programs



By Jamesy0627144 - Derived from BlankMap-World.svg and BlankMap-World6-Subdivisions.svg., CC BY-SA 4.0, <https://commons.wikimedia.org/w/index.php?curid=71821752>

## Why is Accreditation Important to the Cannabis Industry?

- Most states require cannabis laboratories to be accredited
  - ISO 17025 is most common, ORELAP accreditation required in Oregon
    - Confidence that products are tested by a competent laboratory
    - Confidence that laboratories have consistent processes and practices
    - Confidence that the laboratory is committed to good laboratory and ethical practices
- Calibrated Instruments
  - Proficiency Testing
  - Documentation
  - Validated Methods
  - Employee Training
  - Routine Audits





# United States – Specific Challenges

## ■ Federally illegal

- Restricts access to financial/legal services
  - Bank accounts, loans, leases/mortgages, tax incentives, insurance
  - Publically traded companies often will not provide services
  - Prevents access to federal assistance programs (e.g. during COVID)
- Complicates a nationwide Proficiency Testing (PT) program

## ■ Regulations established on a state by state basis

- Large variance in requirements
- May be influenced by industry lobbyists without regard to consumer safety

## ■ Quality requirements vary by state

- Testing for different contaminants
  - Utilization of different testing methodologies
- Different acceptance levels
  - Samples that fail in one jurisdiction may pass in a different jurisdiction



# United States – Range of Contaminant Action Limits



## ■ Residual Solvents

– Butane: not required ----- 12 ppm ----- 800 ppm ----- 5,000 ppm

## ■ Heavy Metals

– Lead: not required ----- 500 ppb ----- 10,000 ppb

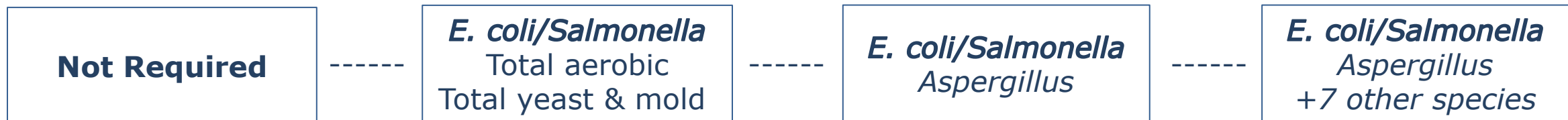
## ■ Mycotoxins

– Aflatoxin: not required ----- 20 ppb

## ■ Pesticides



## ■ Microorganisms



# United States – Sample Collection

- Sample collection requirements varies by state
  - Some states utilize 3<sup>rd</sup> party or laboratory sample collection
- Several states permit producers to select and submit their own samples for testing
  - Samples may be cherry picked, not representative of bulk sample batch
  - Lab samples may be manipulated to increase potency measurements
    - Excessive drying, removal of moisture inflates %THC
    - Samples may be augmented with additional THC (kief)
  - Lab samples may be treated to kill microbial contaminants
    - Bulk sample batch may still contain harmful microorganisms



# Cannabinoid Potency

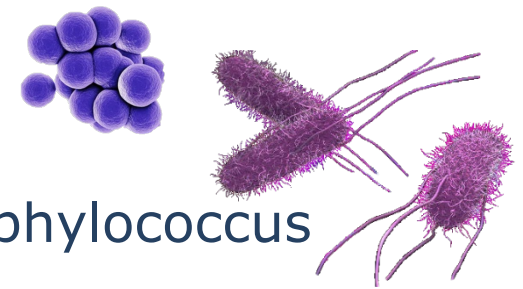
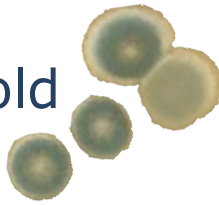
- Highest potency brings the highest retail price
  - Less educated consumers driven by high THC content
- Has led to industry-wide potency inflation challenges
  - Producers may augment their samples prior to testing
  - Laboratories have significant incentive to manipulate samples and/or data
  - Some laboratories advertise *“Highest Potency Results in the Market!”*
- Most states keep cannabis testing data off-limits to public scrutiny
  - Often times little (if any) state-level review of data quality
  - Prevents independent review of collected data





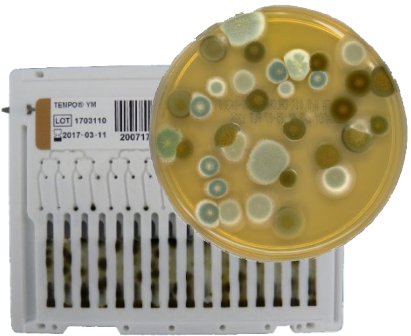
# Microbial Regulatory Approach

- Regulatory action limits may include “Total” counts
  - Total aerobic, total coliform, total bile-tolerant gram negative, total yeast & mold
  - Does not distinguish good from bad microorganisms
  - Product that does not pose risk to consumers may fail, presenting loss to producers
- Regulatory action limits may include only speciated microorganisms
  - Some states only require *E. coli*, *salmonella*, *aspergillus*
  - Assumes these are the only pathogens of concern
  - Does not include other pathogens: *pseudomonas*, *penicillium*, *staphylococcus*
- More recent regulatory limits include a broader combination of both
  - Total counts + several speciated microorganisms
  - Testing gets expensive for producers



# Microbial Testing Methods

- Measurement of microorganisms is impacted by choice of testing method



<p><b>Culture Based Assays</b> Relies on growth of microorganisms</p> <ul style="list-style-type: none"> <li>- Culture Plates</li> <li>- PetriFilms</li> <li>- Most Probably Number</li> </ul>	<p><b>Pros</b></p> <ul style="list-style-type: none"> <li>- Long history of use in food safety</li> <li>- Detailed in the FDA Bacteriological Analytical Manual (BAM)</li> <li>- Has been certified for use in cannabis by AOAC</li> <li>- Low cost equipment</li> </ul>	<p><b>Cons</b></p> <ul style="list-style-type: none"> <li>- Growth can be dependent on culture media selection</li> <li>- Non-selective growth</li> <li>- Longer turn-around times necessary to grow cultures</li> <li>- Not all microbes can be cultured (False Negatives)</li> </ul>
<p><b>Molecular Based Assays</b> Identification of species specific molecules (DNA)</p> <ul style="list-style-type: none"> <li>- PCR</li> <li>- qPCR</li> <li>- MicroArray</li> <li>- ELISA</li> </ul>	<p><b>Pros</b></p> <ul style="list-style-type: none"> <li>- Best approach for species identification (specificity)</li> <li>- High sensitivity</li> <li>- Rapid turn-around times</li> <li>- High throughput</li> <li>- Automation</li> </ul>	<p><b>Cons</b></p> <ul style="list-style-type: none"> <li>- Primer choice is critical</li> <li>- False positives from DNA of non-viable microorganisms</li> <li>- False negatives from use of inappropriate primer</li> <li>- High risk of cross contamination</li> <li>- Instrument and supplies can be expensive</li> </ul>



# Economic Pressures

- Regulated cannabis production is expensive
  - Licensing fees, real-estate, insurance, production supplies, testing requirements, HR requirements, taxes, financial services, municipality payments
- Black market
  - Many expenses detailed above don't apply. Low overhead leads to lower prices
  - Pervasive use of pesticides
  - Synthetic cannabinoids and analogs
  - No quality requirements means highly contaminated consumer supply
  - High risk to consumer safety (EVALI, contaminants, synthetic cannabinoids)
- Puts financial infrastructure of regulated market at risk
  - Oversupply and black market push retail prices and margins down
  - In Massachusetts, retail flower price dropped 42% in last year
    - Good for consumers, until regulated market collapses

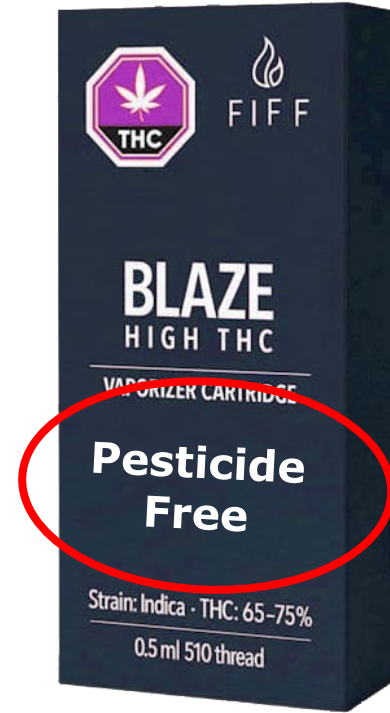


# Pesticides in Vape Cartridges

MRM of 2 Channels ES+

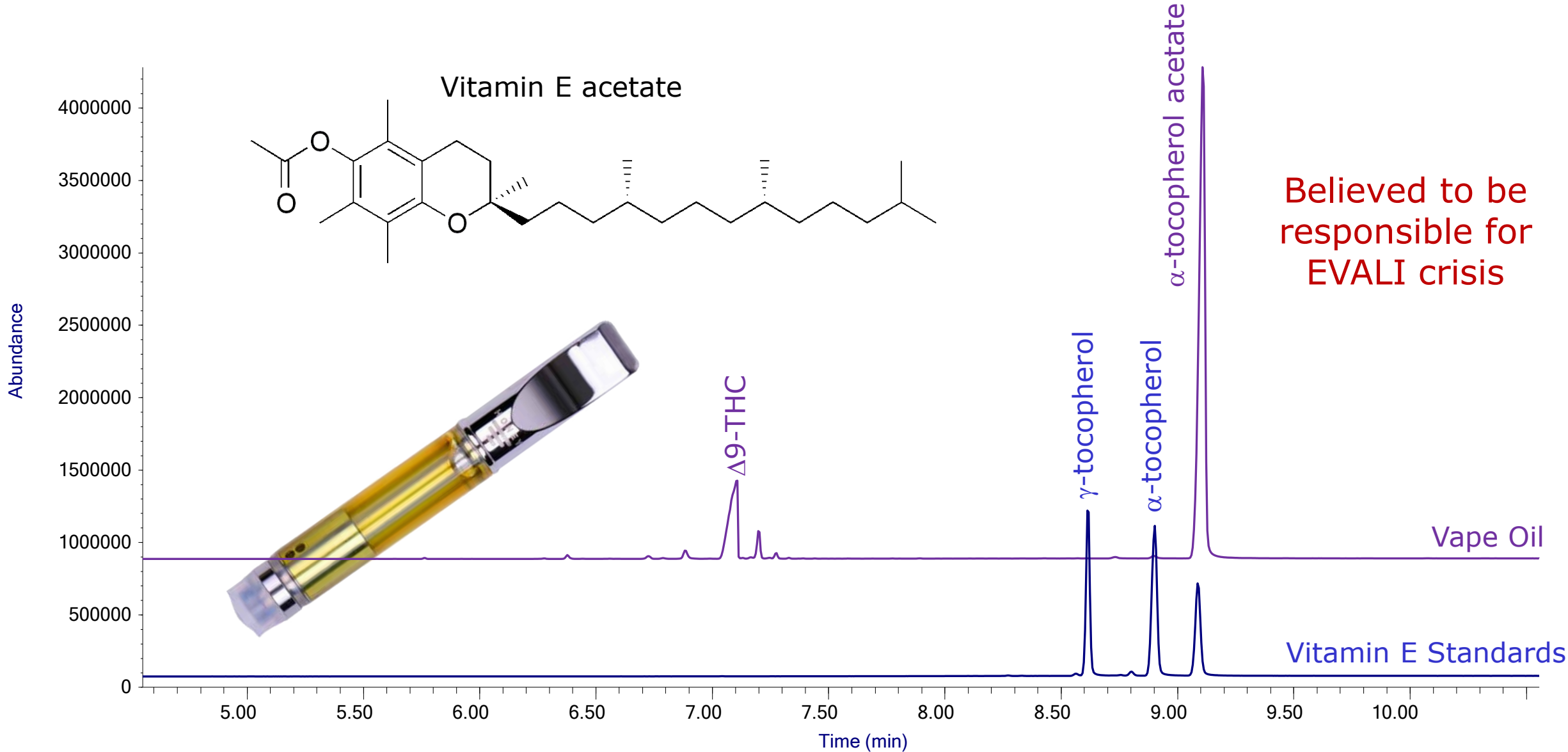
71266-250

Residue	Level (ng/g)
Bifenazate	32,920
Bifenthrin	296,663
Cyfluthrin	19,422
Etoxazole	463
Imidacloprid	809
Myclobutanil	22,277
Paclobutrazol	769
Piperonyl Butoxide	934
Spiromesifen	744
Spirotetramat	75
Carbaryl	8,024
Carbofuran	6,009
Metalaxyl	5,205
Diazinon	578
Tebuconazole	16,163
Malathion	58,086
Chlorantraniliprole	950

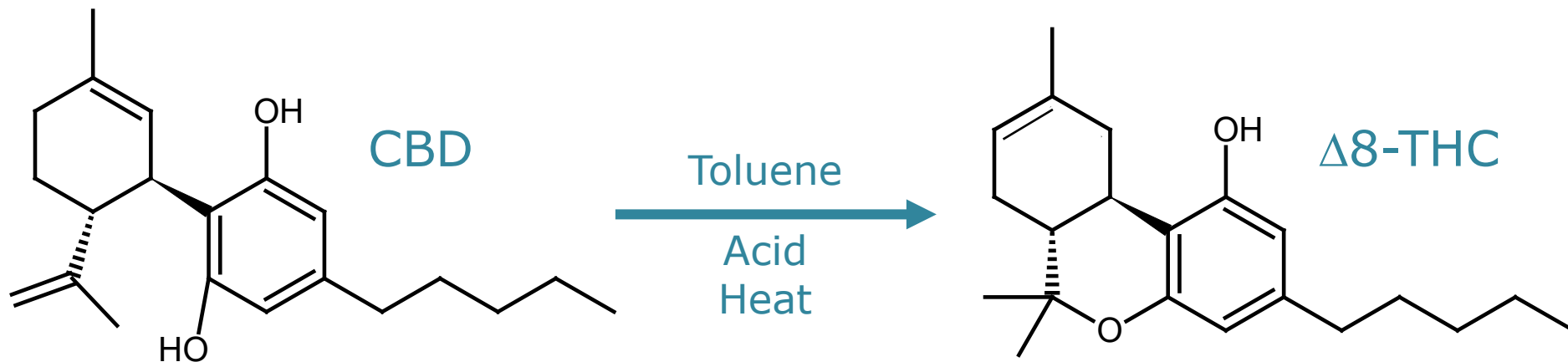




# Additives in Vape Cartridges

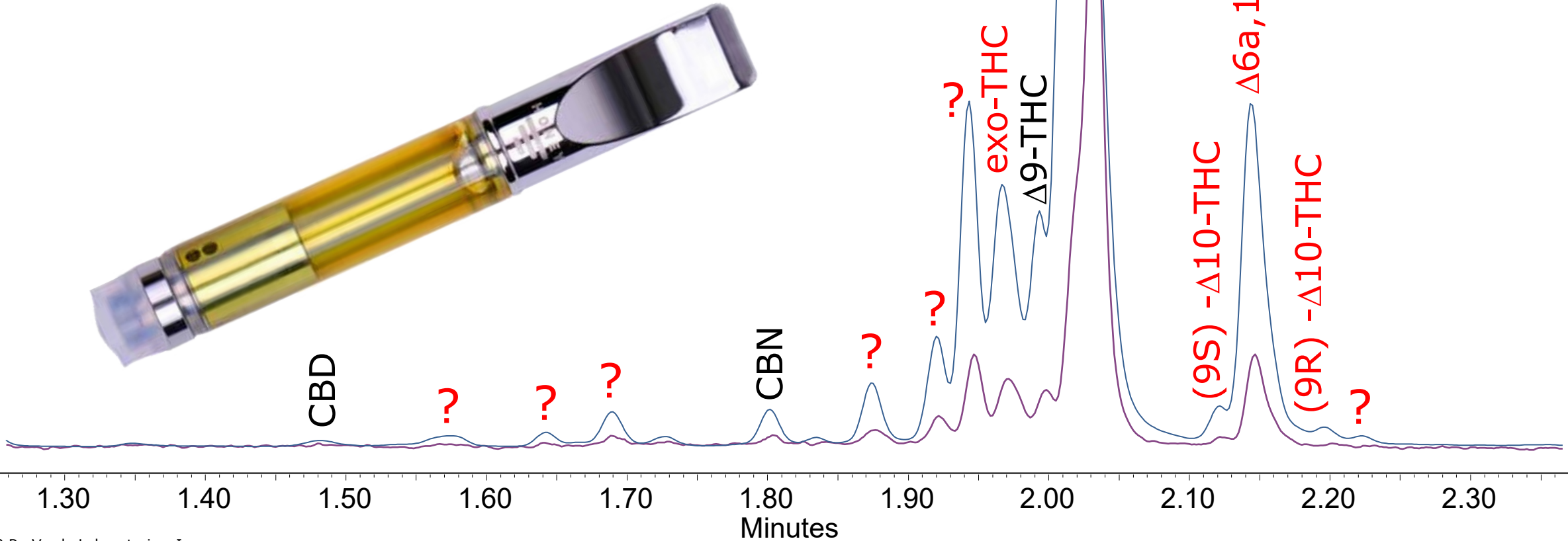


*The term "synthetic" refers to chemical compounds created through a chemical process by human agency, as opposed to those of natural origin. These compounds can be synthesized to imitate a natural product (e.g.  $\Delta 9$ -THC), or they can be synthesized to create a compound not found naturally (e.g.  $\Delta 9$ -THCPO).*

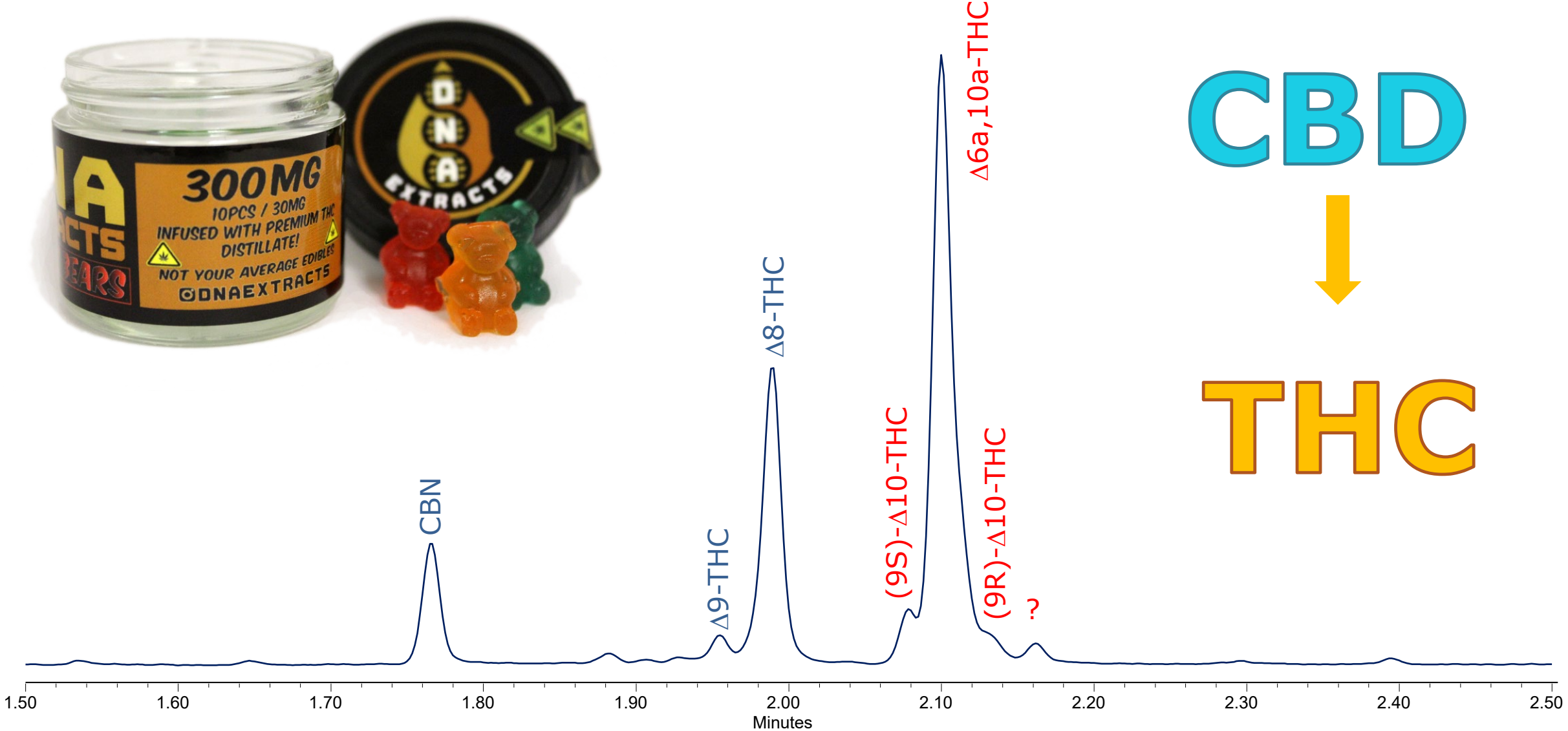


# Synthetic Cannabinoids – in Vape Products

Significant concentrations of un-natural isomers and synthetic byproducts.  
**\* No toxicity information available \***



# Synthetic Cannabinoids – in Edibles



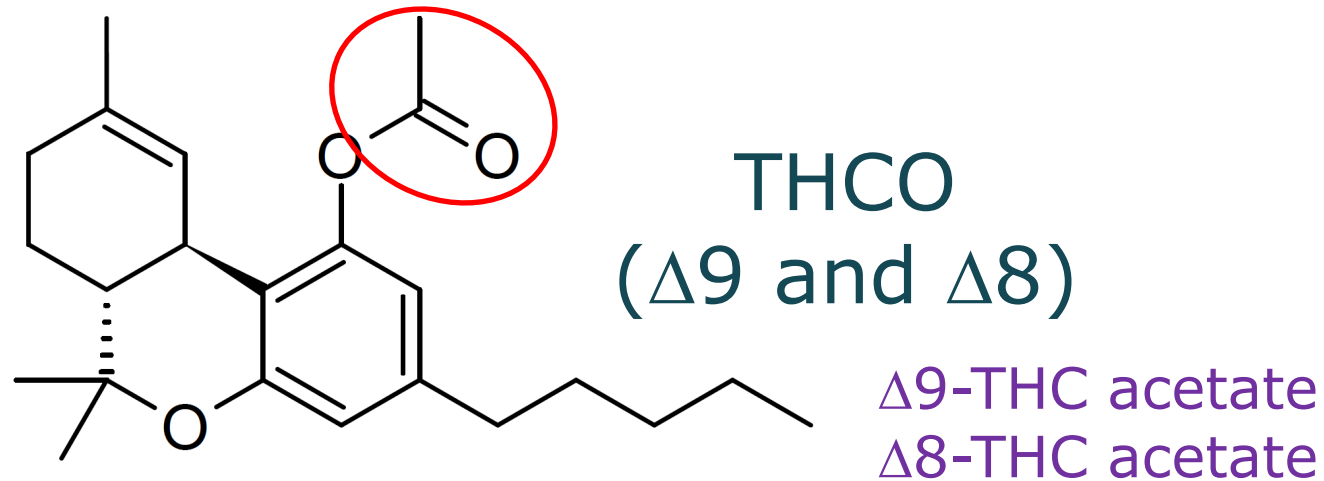
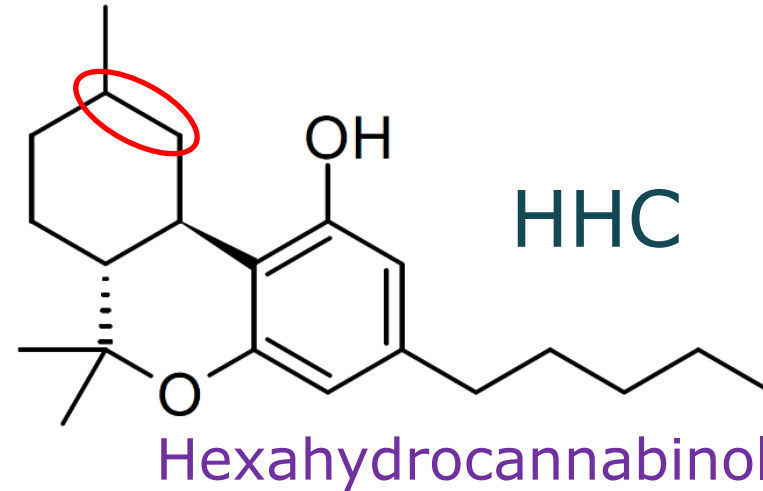
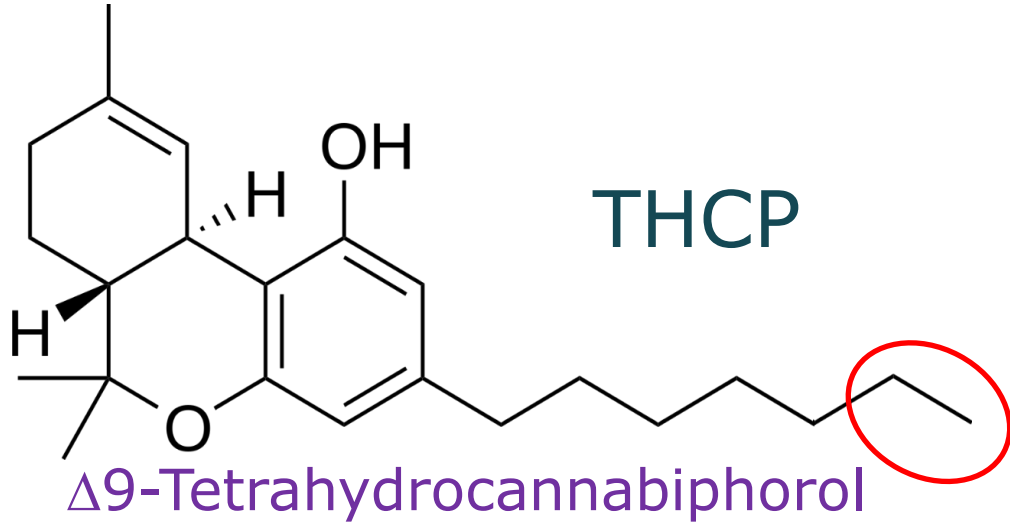
CBD



THC



# Synthetic Cannabinoids – New analogs



- ( $\Delta^9$  /  $\Delta^8$ )
- THCb
  - THCh
  - THCp
  - THCO
  - THCPO
  
  - CBNO
  - HCC
  - HHCP
  - HHCO
  - HHCPO


Not found naturally  
No toxicity information

# Synthetic Cannabinoids – Mixtures

INGREDIENTS: 1000 MG Total Extracts.  
 HHC, D8THC, THCo, CBG, CBN & Live Resin Terpenes.

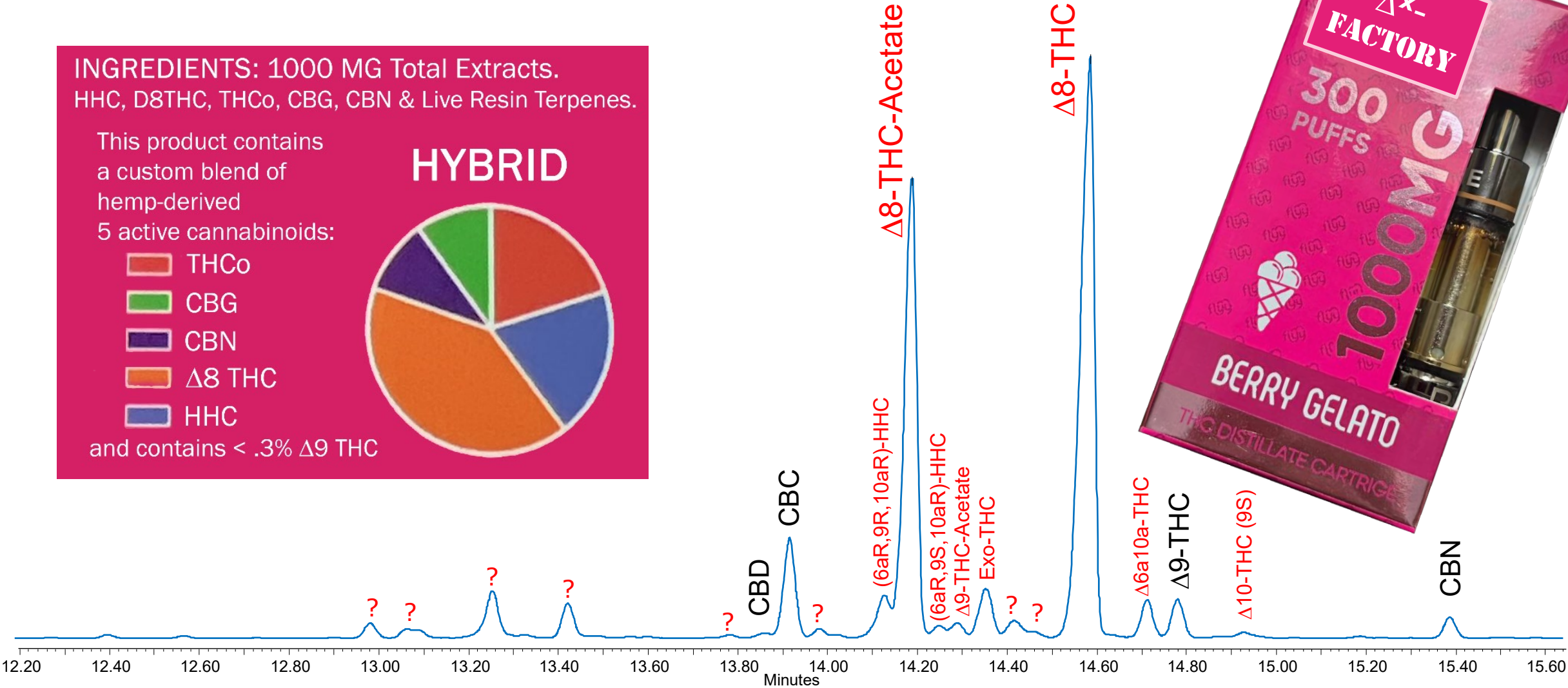
This product contains a custom blend of hemp-derived 5 active cannabinoids:

**HYBRID**

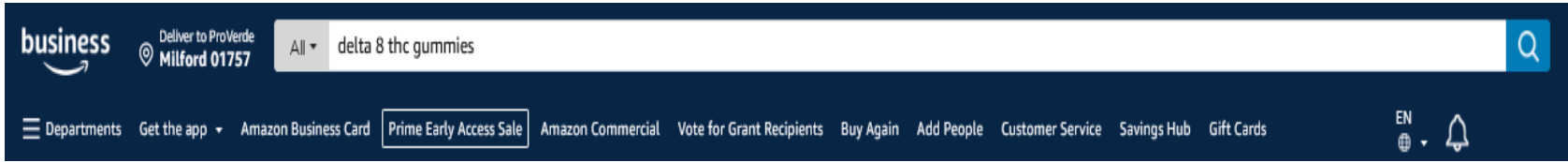


- THCo
- CBG
- CBN
- Δ8 THC
- HHC

and contains < .3% Δ9 THC



# Synthetic Cannabinoids – Widely Available



Hemp Gummies Delta Premium 500 Milligram High Potency - 25 Per Fruity Gummy - Stress Relief, Inflammation, Pain, Restful Sleep

Brand: Generic

★★★★☆ 379 ratings | 17 answered questions

Price: \$29.95 (\$1.50 / Count)

Coupon:  Save an extra 15% when you apply this coupon Terms

Get \$150 off: Pay \$0.00 \$29.95 upon approval for the Amazon Business Card. Terms apply.

Brand	Generic
Item Form	Chewable
Flavor	Hemp
Product Benefits	Stress Relief
Unit Count	20.00 Count
Dosage Form	500-1000
Number of Items	1

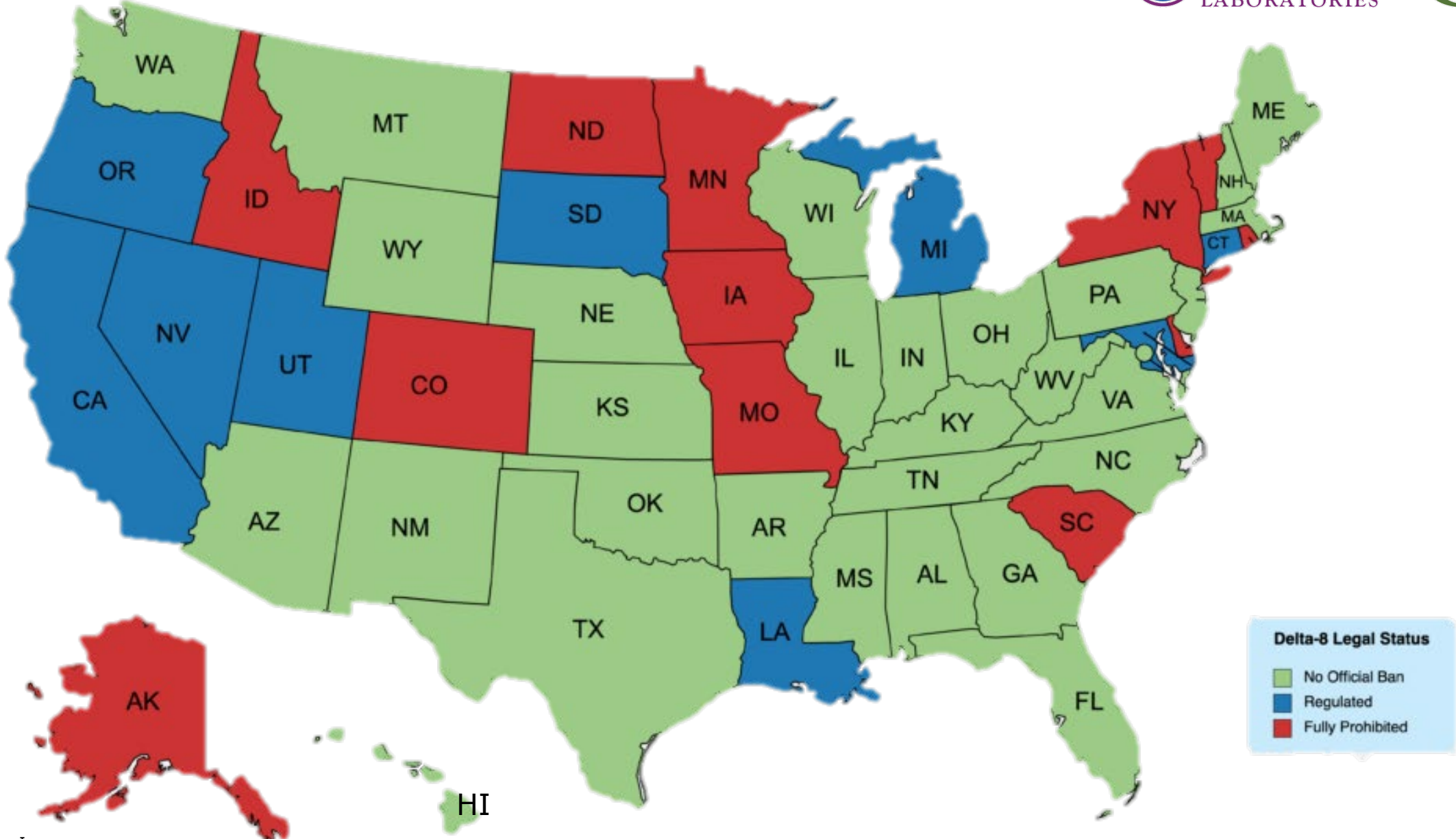
#### About this item

- RELAX- Fight the stresses of the day naturally, and feel the calming and relaxing benefits
- SLEEP- Fall asleep and stay asleep. No more tossing and turning.
- ANXIETY- Calm an overactive mind and stop the constant worrying
- NAUSEOUS- Prevent and combat the feelings of nauseous and stimulate a healthy appetite
- MADE IN USA- Proudly made and packaged in the USA

- Available on Amazon.com
- No mention of THC
- No mention of  $\Delta 8$
- No warning on psychoactivity
- No Age restriction for purchase



# Δ8-THC Legal Status





# Synthetic Cannabinoids – Consumer Safety



**CEN** CANNABIS EQUIPMENT NEWS

VIDEO ADVERTISE NEWSLETTER SIGNUP PODCAST

Cultivation Distribution Extraction Manufacturing New Products News Packaging Processing

VIDEO

## Four Dead After Using Synthetic Cannabis Containing Rat Poison

There were a total of 52 cases of people affected with coagulopathy, a bleeding disorder.

By – Ben Munson, Editor, Cannabis Equipment News, Unit 202 Productions, Eric Sorensen

Oct 11, 2022

NEWS FREE NEWSLETTER EVENTS BUSINESS DIRECTORY HT MAGAZINE SERVICES ABOUT CONTACT

TOP STORIES ON HT CHILD'S DEATH ATTRIBUTED TO DELTA-8 THC IS ANOTHER BLOW TO CBD SECTOR

CBD, LEGAL, NEWS, NORTH AMERICA, REGULATORY, USA

## Child's death attributed to delta-8 THC is another blow to CBD sector

Published 7:47 PM EDT, Fri October 21, 2022

# Summary

- Cannabis safety is complicated by jurisdictional variance
  - Contaminants to be evaluated and tolerance limits vary significantly
- Challenges can be exacerbated by weak/ineffective regulations
  - Product sampling, potency inflation, pesticide testing, microbial contaminants
- Black market poses multiple threats to the regulated cannabis industry
  - Undercutting prices drives consumers to the unregulated market
  - Absence of quality standards poses significant risk to consumer safety
  - Prevalence of synthetic products on the market presents unknown hazards
- Standardized methods and proficiency testing will help to address many of these challenges
- Ultimate goal would be for global harmonization of standards!

# Thank You!



[www.ProVerdeLabs.com](http://www.ProVerdeLabs.com)