



Español

Delta-8 tetrahydrocannabinol, also known as delta-8 THC, is a psychoactive substance found in the *Cannabis sativa* plant, of which marijuana and hemp are two varieties. Delta-8 THC is one of over 100 cannabinoids produced naturally by the cannabis plant but is not found in significant amounts in the cannabis plant. As a result, concentrated amounts of delta-8 THC are typically manufactured from hemp-derived cannabidiol (CBD).

It is important for consumers to be aware that delta-8 THC products have not been evaluated or approved by the FDA for safe use in any context. They may be marketed in ways that put the public health at risk and should especially be kept out of reach of children and pets.

Here are 5 things you should know about delta-8 THC to keep you and those you care for safe from products that may pose serious health risks:

1. Delta-8 THC products have not been evaluated or approved by the FDA for safe use and may be marketed in ways that put the public health at risk.

The FDA is aware of the growing concerns surrounding delta-8 THC products currently being sold online and in stores. These products have not been evaluated or approved by the FDA for safe use in any context. Some concerns include variability in product formulations and product labeling, other cannabinoid and terpene content, and variable delta-8 THC concentrations. Additionally, some of these products may be labeled simply as “hemp products,” which may mislead consumers who associate “hemp” with “non-psychoactive.” Furthermore, the FDA is concerned by the proliferation of products that

contain delta-8 THC and are marketed for therapeutic or medical uses, although they have not been approved by the FDA. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of federal law, but also can put consumers at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns because patients and other consumers may use them instead of approved therapies to treat serious and even fatal diseases.

2. The FDA has received adverse event reports involving delta-8 THC-containing products.

The FDA received 104 reports of adverse events in patients who consumed delta-8 THC products between December 1, 2020, and February 28, 2022. Of these 104 adverse event reports:

- 77% involved adults, 8% involved pediatric patients less than 18 years of age, and 15% did not report age.
- 55% required intervention (e.g., evaluation by emergency medical services) or hospital admission.
- 66% described adverse events after ingestion of delta-8 THC-containing food products (e.g., brownies, gummies).
- Adverse events included, but were not limited to: hallucinations, vomiting, tremor, anxiety, dizziness, confusion, and loss of consciousness.

National poison control centers received 2,362 exposure cases of delta-8 THC products between January 1, 2021 (i.e., date that delta-8 THC product code was added to database), and February 28, 2022. Of the 2,362 exposure cases:

- 58% involved adults, 41% involved pediatric patients less than 18 years of age, and 1% did not report age.
- 40% involved unintentional exposure to delta-8 THC and 82% of these unintentional exposures affected pediatric patients.
- 70% required health care facility evaluation, of which 8% resulted in admission to a critical care unit; 45% of patients requiring health care facility evaluation were pediatric patients.
- One pediatric case was coded with a medical outcome of *death*.

3. Delta-8 THC has psychoactive and intoxicating effects.

Delta-8 THC has psychoactive and intoxicating effects, similar to delta-9 THC (i.e., the component responsible for the “high” people may experience from using cannabis). The FDA is aware of media reports of delta-8 THC products getting consumers “high.” The FDA is also concerned that delta-8 THC products likely expose consumers to much higher levels of the substance than are naturally occurring in hemp cannabis raw

extracts. Thus, historical use of cannabis cannot be relied upon in establishing a level of safety for these products in humans.

4. Delta-8 THC products often involve use of potentially harmful chemicals to create the concentrations of delta-8 THC claimed in the marketplace.

The natural amount of delta-8 THC in hemp is very low, and additional chemicals are needed to convert other cannabinoids in hemp, like CBD, into delta-8 THC (i.e., synthetic conversion). Concerns with this process include:

- Some manufacturers may use potentially unsafe household chemicals to make delta-8 THC through this chemical synthesis process. Additional chemicals may be used to change the color of the final product. The final delta-8 THC product may have potentially harmful by-products (contaminants) due to the chemicals used in the process, and there is uncertainty with respect to other potential contaminants that may be present or produced depending on the composition of the starting raw material. If consumed or inhaled, these chemicals, including some used to make (synthesize) delta-8 THC and the by-products created during synthesis, can be harmful.
- Manufacturing of delta-8 THC products may occur in uncontrolled or unsanitary settings, which may lead to the presence of unsafe contaminants or other potentially harmful substances.

5. Delta-8 THC products should be kept out of the reach of children and pets.

Manufacturers are packaging and labeling these products in ways that may appeal to children (gummies, chocolates, cookies, candies, etc.). These products may be purchased online, as well as at a variety of retailers, including convenience stores and gas stations, where there may not be age limits on who can purchase these products. As discussed above, there have been numerous poison control center alerts involving pediatric patients who were exposed to delta-8 THC-containing products. Additionally, animal poison control centers have indicated a sharp overall increase in accidental exposure of pets to these products. Keep these products out of reach of children and pets.

Why is the FDA notifying the public about delta-8 THC?

A combination of factors has led the FDA to provide consumers with this information. These factors include:

- An uptick in adverse event reports to the FDA and the nation's poison control centers.
- Marketing, including online marketing of products, that is appealing to children.
- Concerns regarding contamination due to methods of manufacturing that may in some cases be used to produce marketed delta-8 THC products.

The FDA is actively working with federal and state partners to further address the concerns related to these products and monitoring the market for product complaints, adverse events, and other emerging cannabis-derived products of potential concern. The FDA will warn consumers about public health and safety issues and take action, when necessary, when FDA-regulated products violate the law.

How to report complaints and cases of accidental exposure or adverse events:

If you think you are having a serious side effect that is an immediate danger to your health, call 9-1-1 or go to your local emergency room. Health care professionals and patients are encouraged to report complaints and cases of accidental exposure and adverse events to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Call an FDA [Consumer Complaint Coordinator](#) if you wish to speak directly to a person about your problem.
- Complete an [electronic Voluntary MedWatch form](#) online or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form, or submit by fax to 1-800-FDA-0178.
- Complete a [paper Voluntary MedWatch form](#) and mail it to the FDA.
- To report adverse events in animals to the FDA's Center for Veterinary Medicine, please download and submit Form FDA 1932a found at: www.fda.gov/ReportAnimalAE.