



## AMERICAN KRATOM ASSOCIATION

Vendor Advisory  
April 16, 2024

For more information, contact:  
Mac Haddow, Senior Fellow on Public Policy  
Cell: (571) 294-5978  
Email: mhaddow@americankratom.org

### VENDOR ADVISORY ON ENHANCED 7-HYDROXYMITRAGYNE (“7-OH”) PRODUCTS

*All vendors and retailers are advised that the American Kratom Association (AKA) is strongly opposed to the market entry of products that isolate, purify, or concentrate the 7-OH metabolite above levels that naturally occur in the kratom plant. These products are currently illegal for sale under federal and many state laws.*

**GAINESVILLE, VA** — The AKA has, in its Kratom Consumer Protection Act (KCPA) lobbying efforts, recommended language that limits 7-OH content in a kratom product to no more than 2% of the total alkaloid fraction of the overall constituent content of the kratom plant. In some states, that limit is not to exceed 1%. Any kratom product containing 7-OH at a higher level is illegal for sale in those states.

Here are the reasons for our Advisory on 7-hydroxymitragynine products:

- A 7-OH synthetically enhanced product IS **NOT A KRATOM PRODUCT AND SHOULD NOT BE LABELED WITH ANY REFERENCE TO “KRATOM.”**
- It is standing FDA policy that a synthetic copy of a botanical or constituent of a botanical **DO NOT** meet the FDCA’s definition of a dietary ingredient.<sup>1</sup>
- There is currently no valid scientific literature of which the AKA is aware that supports any claim that enhanced or synthetic 7-OH is safe, particularly at artificially increased levels.
- The consensus of leading scientists is that 7-OH enhanced products have a greater abuse liability and a higher risk for adverse events.
- 7-OH enhanced and synthetic products are likely “adulterated” under the Food, Drug, and Cosmetics Act and expose retailers to significant risks of legal and regulatory issues.

The reason for this warning on enhanced and synthetic 7-OH is simple. The AKA believes that every policy decision on kratom should be based on reliable and published scientific research. To date, the AKA is not aware of any published literature documenting the safety profile of artificially isolated or concentrated 7-OH products, and leading kratom scientists recently issued a clear warning about isolated 7-OH products:

---

<sup>1</sup> U.S. Food and Drug Administration. (August 2016). *Dietary Supplements: New Dietary Ingredients Notifications and Related Issues: Guidance For Industry, Draft Guidance*. Washington DC.

*Further, any semi-synthetic, isolated kratom alkaloid, and selective alkaloid rich fraction would, we believe, pose considerable risk in an unregulated product, and would no longer be considered as “kratom” in any meaningful sense of the term.<sup>2</sup>*

7-OH has an extremely complicated pharmacologic activity in the human body, and when isolated and concentrated it has been reported to have a relatively greater abuse liability than its parent, mitragynine.

Accordingly, unless and until reliable, peer-reviewed published research is available documenting the safety profile of isolated, concentrated, or enhanced 7-OH products, the AKA strongly recommends vendors and retailers not produce, distribute, or sell any so-called “7-OH” product. While some 7-OH product manufacturers may not include the “kratom” name on their packaging, listing the parent alkaloid mitragynine from which 7-OH is derived will clearly mislead consumers into thinking it is an otherwise safe kratom product.

Marketing of an isolated, enhanced, or concentrated 7-OH product will also mislead federal and state regulators and will inevitably restart efforts to ban legitimate kratom products. Marketing of isolated, enhanced, or concentrated 7-OH products will also create significant confusion in the kratom marketplace and will likely expose any vendor or retailer to significant legal and regulatory liability.

*The American Kratom Association (AKA), a consumer-based non-profit organization, advocates to protect the freedom of consumers to safely consume natural kratom as a part of their personal health and well-being regimen. AKA represents the more than 15 million Americans who consume kratom safely.*

[www.amerikankratom.org](http://www.amerikankratom.org)

---

<sup>2</sup> [https://assets.website-files.com/61858fcec654303987617512/660d76df95f338f4831ef792\\_Statement%20on%20the%20science%20of%20kratom%20products\\_FINAL.pdf](https://assets.website-files.com/61858fcec654303987617512/660d76df95f338f4831ef792_Statement%20on%20the%20science%20of%20kratom%20products_FINAL.pdf)