GLOBAL KRATOM COALITION

Statement on 7-Hydroxymitragynine Products

Kratom is a complex plant that contains at least 40 different alkaloids that work together as a 'complex symphony orchestra', giving kratom its unique effects. As advocates for the responsible manufacture, use, and regulation of kratom products, the Global Kratom Coalition has a deep concern with respect to the rise in products being sold and marketed as 'kratom' in the U.S. that contain enhanced kratom alkaloids or their synthetically derived analogues.

One such case is the rise in products containing isolated, synthetic 7-hydroxymitragynine (7OH) that are being marketed as kratom products.

In a recent statement put forward by leading kratom scientists, they state that the pharmacology of 7OH is different from mitragynine in that 7OH acts primarily through opioid receptors. The statement also clarifies that 7OH is not a natural component of the kratom leaf, is only found in very low levels in kratom leaf material as a degradation product, and that most properly manufactured US kratom products do not contain 7OH in meaningful amounts. From a safety perspective, these leading scientists endorse limiting the amount of 7OH in kratom-derived products.

When reviewing the Certificate of Analysis for a leading 7OH product, the results show that the levels of mitragynine and other truly kratom-derived alkaloids in the product are either non-existent or much lower than that found in authentic kratom products. On the other hand, the level of 7OH found in the product is orders of magnitude higher than what is found in authentic kratom products.

The Kratom Consumer Protection Act in California limits the amount of 7OH to a maximum of 1% of the total alkaloids found in a kratom product. According to its label, the leading 7OH tablet that is being sold contains 14 mg of 7OH. Under the conditions set out in the Kratom Consumer Protection Act in California the amount of 7OH that is apparent in this specific 7OH product is orders of magnitude higher than what would be consumed when using a kratom product, even at high serving levels, as shown in table (i):

Table (i):

Product Type	Commercial Kratom Product		
	25mg Alkaloid Serving	50mg Alkaloid Serving	100mg Alkaloid Serving
Amount of 7-hydroxymitragynine if at 1%	0.25mg	0.5mg	1mg
Amount 7-hydroxymitragynine compared to 7OH product	56 times higher	28 times higher	14 times higher

In reality, most kratom products contain very small or undetectable amounts of 7OH, and as such, the levels of 7OH are even lower than what is indicated in table (i).

To our knowledge, no clinical research has been performed for isolated 7OH, but based on what is known about 7OH from other studies, the safety of this compound when consumed in isolation holds a significant level of concern. Additionally, in vitro receptor binding studies have shown that 7OH has a much higher affinity for opioid receptors relative to mitragynine, which gives rise to concerns for 7OH when sold in formats with high levels of concentration.

Leaf kratom, which has a long, safe history of use, has been the subject of significant scientific research, including both past and ongoing preclinical and clinical studies and is defined as a New Dietary Ingredient (NDI) by the FDA. There is, however, a strong case that shows leaf kratom is, in fact, an Old Dietary Ingredient (ODI).

It has been stated that the intended use for these 7OH products is as an alternative to opioids, which is a therapeutic or drug-substitution type claim that can only be made by an FDA-approved drug. As such, the regulatory pathway appropriate for 7OH used for this indication only aligns with its development as a drug and should be conducted under an Investigation New Drug (IND) application.

Synthetic 7OH products lack the documented traditional use, preclinical, and clinical data that supports the use of kratom products. There must be a distinction made between kratom products and synthetic compounds that are structurally related to the alkaloids found in kratom. Simply put, any synthetic derivatization is not “kratom” and needs to be carefully assessed as to its classification and its regulatory path to market.

In the interest of public health, taking into account the gaps surrounding its regulation, potential risks, and the need for comprehensive research, the Global Kratom Coalition is opposed to the integration of 7OH into the existing kratom product supply chain.

For more information:

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