



Kratom Product Label and Packaging Guidance

This document provides a summary of all packaging and labeling requirements to ensure compliance with the [Rhode Island Kratom Act](#).

Product Form Requirements

- Product must be intended for oral consumption only:
 - Product cannot be a conventional food or beverage.
 - Product cannot mimic candy or be marketed to appeal to individuals under 21 years of age.
 - Product cannot be combustible, injectable, vaped, or aerosolized.

Alkaloid Content

Products must be clearly labeled per serving to ensure that they meet the concentration ratios set forth in the Rhode Island Kratom Act. No synthetic alkaloids are allowed in any kratom products sold in Rhode Island. The concentration ratio limits are as follows:

Mitragynine	≤ 150 mg per serving
7-hydroxymitragynine	≤ 1 mg per serving ≤ 0.5 mg per gram ≤ 1% of total alkaloids

Product labels must include the following alkaloid content with the units listed below:

	Per Serving	Per Product
Mitragynine	mg	mg
7-hydroxymitragynine	mg	mg
Total Alkaloids	mg	mg
7-hydroxymitragynine	mg per gram	

Dosage & Serving Instructions

- Recommended serving size must be clearly stated on the label.
- Recommended number of servings per 24-hour period must be indicated on the label.

Safety Warnings

Labels must clearly and visibly include the following warning statements:

- Consult a health care professional prior to use.
- Kratom may be habit forming.
- Kratom is not safe for use while pregnant or breastfeeding.
- This product may result in dangerous medication interactions.
- This product should be stored safely and out of the reach of children.

Regulatory Disclaimer

The following FDA disclaimer must be on the label:

“These statements have not been evaluated by the United States Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”

Net Quantity & Packaging Requirements

- Declare net quantity in numerical count (e.g., capsules), weight, or volume in US customary units (g, oz, mL, fl oz) on the label.
- Must be in child-resistant packaging per [16 C.F.R. 1700.15\(b\)](#) and [16 C.F.R. 1700.20](#).

Manufacturer / Distributor Information

- Include name of the manufacturer or distributor on the label.
- Include a physical, non-PO box address on the label.

Other Safety Requirements

All kratom products sold in Rhode Island must meet applicable safety requirements and must not include:

- Any kratom product that contains a substance that is poisonous, harmful, or otherwise injurious to health.
- Any kratom product that contains a substance other than a non-psychoactive substance necessary for the preparation, processing, or manufacturing of the product.
- Any kratom extract that contains residual solvent levels exceeding those permitted under the most current version of U.S. Pharmacopeia 467.
- Any kratom product containing synthetic alkaloids, including but not limited to synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compounds of the kratom plant.
- Any kratom product containing heavy metals in excess of the following limits (parts per million): arsenic (<2), cadmium (<0.82), lead (<1.2), and mercury (<0.4).

Testing and verification from an ISO17025 accredited lab may be required to confirm compliance with these requirements.



Kratom Product Label Example

Disclaimer: This example only includes the requirements of the Rhode Island Kratom Act. Please ensure your labels meet the requirements of any federal labeling laws and any other applicable laws or regulations.

KRATOM PRODUCT	SERVING SIZE AND ALKALOID CONTENT:		
	Serving Size: XX Capsules per serving.		
	Maximum dosage: Do not take more than XX servings in 24 hours.		
		Per Serving	Per Product
	Mitragynine	mg	mg
7-hydroxymitragynine	mg	mg	
Total Alkaloids	mg	mg	
7-hydroxymitragynine	mg per gram		

WARNING: <ul style="list-style-type: none">• Consult a health care professional prior to use.• Kratom may be habit forming.• Kratom is not safe for use while pregnant or breastfeeding.• This product may result in dangerous medication interactions.• This product should be stored safely and out of the reach of children.	This product is only intended for individuals 21+
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<i>These statements have not been evaluated by the United States Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.</i>

Manufacturers Name and Full Adress: ADD NAME AND ADDRESS

Net Quantity: XX Capsules/Weight/Volume
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NOTE: Kratom products must be in child-resistant packaging per [16 C.F.R. 1700.15\(b\)](#) and [16 C.F.R. 1700.20](#).