

Kratom Product Registration

FORM **230**

1 Do you hold, or have you previously held, a Nebraska ID number? YES NO If Yes, provide the number: 2 Federal Employer ID Number				Please Do Not Write In This Space				
Name and Location Address of Business				N.	me an	d Mailing Address		
Name (dba)				Name and Mailing Address Name				
Legal Name								
Business Street Address (Do Not Use PO Box)				Street or Other Address				
City	State		ZIP Code	City		State	ZIP Code	
Country				Country				
3 Reason for Filing Registration Initial Registration — Kratom manufacturer is not currently listed on the Nebraska Directory of Certified Kratom Manufacturers Annual Registration for calendar year Supplemental Registration — Change in kratom listed on directory, or other information Provide an explanation if a supplemental registration is being submitted.								
4 Identify Owner, Partners, Members, o	r Corporation O	fficers						
Name Address, City, State,				ZIP Code Title, if Corporate Officer				
5 Type of Ownership						1		
(1) Sole Proprietorship (2) Partnership (3) Corporation (4) Foreign Corporation (another sta		(5) S Corporation (6) Fiduciary (Estate or Trust) (7) Limited Liability Company (LLC) (8) Other						
6 Does the kratom manufacturer affirmatively certify that the kratom manufacturer will comply with all applicable laws of Nebraska? YES NO If No, please explain:								
7 Manufacturing Facility Location								
Address of Facility			City, State	City, State, ZIP Code			Country	
8 Provide a complete listing of kratom products to be sold in Nebraska by completing Form 230 Item 8 in Excel format. The Excel file must include the following information:								
Product Name		SKU	Packaging Type	Package UPC		Units per Package	Status	
8b Total number of kratom products inc	luded in this reg	gistration					. 8b	
9 The following items must be submitted with this application: a. Attach a copy of each product's label. Note: A copy need not be submitted if a copy of the packaging or labeling has been previously provided and it remains unchanged. If so, check box								
For each product, attach a certificate of analysis for the kratom product that states the kratom product's alkaloid content and certifies that the kratom product has a level of 7-hydroxymitragynine that is less than two percent of the alkaloid composition of the kratom product from an independent laboratory. Ensure each certificate identifies the kratom product which is analyzed.								
C. Number of kratom products to be requested to be added with the certification.								
Attach a copy of the valid good manufacturing practice certificate issued by an accredited third-party certification body in compliance with 21 C.F.R. Part 111.								
e. Attach a copy of current food facility registration certificate issued by federal Food and Drug Administration for all facilities where kratom products are manufactured, prepared, packaged or labeled								

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Email. I acknowledge that if an email address is listed and I did not check the "Opt-Out" box, I am allowing DOR to contact me by email. DOR will send all confidential information by secure email or State of Nebraska secure file sharing system. If you do not wish to exchange confidential information by email, check the box labeled "Opt-Out" on the line labeled "email address."

Authorized Signature. This schedule must be signed by the owner, partner, member, corporate officer, or other individual authorized to sign by a power of attorney on file with DOR.

	Under penalties of law, I declare that I have examined the information provided, and to the best of my knowledge and belief, it is correct and comp								
sign here	Authorized Signature	Date	Print Authorized Person's Name						
	Title	Phone Number	Authorized Person's Email Address	Opt-Out					
	Contact Person (if different than Authorized Person)	Phone Number	Contact Person's Email Address	Opt-Out					

Instructions

Who Must File. A manufacturer of kratom products that are sold at retail in this state, whether directly or through a distributor, wholesaler, retailer, or similar intermediary or intermediaries must submit a Certification.

When to File. Beginning January 1, 2026 kratom manufacturers are required to complete the certification. Annual renewal is required. A certification is valid for one calendar year after the date of issuance. For kratom manufacturers making any changes to their initial Certification, the supplemental Certification noting the changes must be submitted at least thirty (30) calendar days prior to that change becoming effective.

Where to File. Submit this application along with the required attachments using <u>DOR's secure file sharing system</u>. Mail Kratom Product Registration Payment Voucher, Form 230-V with the application fee to Nebraska Department of Revenue, PO Box 98903, Lincoln, NE 68509-8903. Checks should be made out to the Nebraska Department of Revenue.

Fees. There is a nonrefundable \$750 fee per kratom product. Kratom products that contain the same kratom ingredients in the same kratom delivery form, but are packaged, sold, or offered for sale in a different container, package, or volume are included in a single registration fee.

Definitions. Kratom product has the same meaning as prescribed in Neb. Rev. Stat. § 71-3802(5).

- 1. Kratom means the plant mitragyna speciosa or any part of that plant, including, but not limited to, all components present in the natural plant;
- 2. Kratom extract means the material obtained by extraction of kratom leaves with a solvent consisting of water, ethanol, or food-grade carbon dioxide, or any other solvent allowed by federal or state regulation to be used in manufacturing a food ingredient;
- 3. Kratom product means a food, ingredient, or dietary supplement that:
 - a. Consists of or contains kratom or kratom extract;
 - b. Does not contain any synthesized kratom alkaloids, other synthesized kratom constituents, or synthesized metabolites of any kratom constituent;
 - c. Does not contain a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than two percent of the alkaloid composition of the kratom product; and
 - d. Does not include any kratom product in any form that is combustible, is intended to be used for vaporization, or is injectable;
- 4. Processor means a person or business that manufactures, packages, labels, or distributes kratom products or advertises, represents, or holds itself out as manufacturing, preparing, packaging, labeling, or distributing kratom products;
- 5. Retailer has the same meaning as in Neb. Rev. Stat. § 77-2701.32; and
- 6. Synthesized means an alkaloid or alkaloid derivative that has been created, in full or in part, by directed chemical, physical, or biosynthetic conversion, including, but not limited to, fermentation, recombinant techniques, yeast-derived, or enzymatic techniques, rather than traditional food preparation techniques, such as heating or extracting.

Records Retention Requirement. Kratom manufacturers must maintain all invoices and documentation of sales and other information relied upon for the certification for a period of three years, unless otherwise required by law to maintain them for a greater period of time.

Item 3. For annual registration, list four digit calendar year. All registrations will expire on December 31 of each year.

Item 8. A complete listing of all kratom products of the manufacturer to be sold in Nebraska must be listed. If the kratom product has not been included in an approved prior registration, enter "NEW" in the column status. If the kratom product was included in an approved prior registration, and there is a change related to the kratom product enter "MODIFIED" in the column status.

Item 9a. Attach a copy of each kratom packaging or labeling. Label the attachment as Attachment 9A. Kratom products considered attractive to children cannot be registered.

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Each kratom product must state on each retail package:

(1) The product is not recommended for use by individuals who are under twenty-one years of age, who are pregnant, or who are breastfeeding;

- (2) A health care practitioner should be consulted prior to using the product;
- (3) The product may be habit-forming;
- (4) The following statements: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.";
- (5) The name and place of business of the processor;
- (6) Directions for use that include a recommended amount of the kratom product per serving that is:
 - (a) Clearly described on the label for product forms such as capsules, gummies, prepackaged, single-serving units, and similar product forms; or
 - (b) A clear instruction or a mark on the package or container for beverages or liquids;
- (7) A recommended number of servings that can be safely consumed in a twenty-four-hour period;
- (8) A listing of the servings per container; and
- (9) A listing of kratom alkaloids mitragynine and 7-hydroxymitragynine and other ingredients in the product, including quantitative declarations of the amount per serving of mitragynine.

Any application that is incomplete or deficient and not corrected or supplemented within 30 days after DOR's notification will be denied.